907 KAR 1:479
Incorporation by Reference

MAP-9, Prior Authorization Form
December 1995 Edition
(Clean Copy)

MAP-1000, Certificate of Medical Necessity
June 2003 Edition
(Clean Copy)

Medicare Region C DMERC DMEPOS Supplier Manual
Chapter Six (6), Chapter Eight (8), and
Chapters Eighteen (18) through the Appendices of the 2002 Edition
(Clean Copy)

Medicaid DME Program Fee Schedule
March 1, 2003 Edition
(Clean Copy)

Floor Amendments June 10, 2003

FILED: March 7, 2003

Adopted July 16, 2003

Cabinet for Health Services
Department for Medicaid Services
275 East Main Street
Frankfort KY 40601

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<<BACK

Chapter 6 - Documentation Requirements

View Attachments

Click on View Attachments to view the formatted Manual pages regarding documentation requirements, including information about prior authorization, Certfiicates of Medical Necessity and written orders prior to delivery .

DOCUMENTATION REQUIREMENTS

PHYSICIAN ORDERS

Suppliers must have an order from the treating physician before dispensing a DMEPOS item to a beneficiary. Except for items requiring a written order prior to delivery, the dispensing order may be a written, fax or verbal order. The dispensing order must include:

- A description of the item;
- The beneficiary's name;
- The name of the physician; and
- The date of the order.

DETAILED WRITTEN ORDER

A supplier must also have a detailed order in addition to the dispensing order. The supplier must retain the detailed written order and make it available to the DMERC upon request. The detailed order must include:

- Patient's name;
- A description of the item (the description can be either a narrative or a brand name/model number) and the length of need;
- If the order is for accessories or supplies that will be provided on a periodic basis, it must include appropriate information on the quantity used, frequency of change or use, and length of need;
- If the order is a drug, it must specify the name of the drug, concentration (if applicable), dosage, frequency of administration,

and duration of infusion (if applicable).
- Patient's diagnosis (policy applicable);
- The expected start date of the order;
- The physician's signature and date.

Requirement of New Orders
A new order is required in the following situations:

- There is a change in the order or the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) if specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier/and or physician.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DMERC.

If there is no order (verbal, fax or written) from the doctor upon dispensing, suppliers do not need to file a claim.

WRITTEN ORDERS PRIOR TO DELIVERY
For certain types of durable medical equipment, an order from the physician must be obtained by the supplier prior to delivery of these items. The items subject to this requirement are listed below with the associated HCPCS code. The order must include the patient's full name, a description and the length of need of the item prescribed, appropriate information on the quantity used, frequency of change or use, and length of need for supplies that will be provided on a periodic basis, the expected start date of the order, and the physician's signature and signature date. The written order should be obtained before delivery and kept in the supplier's records. This requirement applies to these items regardless of the intent by the patient and/or supplier to accept or not accept Medicare assignment.

Items Requiring a Written Order Prior to Delivery

Decubitus Care

A4640	Replacement pad for use with medically necessary alternating pressure pad owned by patient
E0176	Air pressure pad or cushion, non-positioning
E0177	Water pressure pad or cushion, non-positioning
E0178	Gel pressure pad or cushion, non-positioning
E0179	Dry pressure pad or cushion, non-positioning (e.g., eggcrate)
E0180	Pressure pad, alternating, with pump

E0181	Pressure pad, alternating, with pump, heavy duty
E0182	Pump for alternating pressure pad
E0184	Dry pressure mattress
E0185	Gel or gel-like pressure pad for mattress, standard mattress length and width
E0186	Air pressure mattress
E0187	Water pressure mattress
E0192	Low pressure and positioning equalization pad for wheelchair (for example, roho, jay, etc.)
E0193	Powered air flotation bed (low air loss therapy)
E0194	Air-fluidized bed
E0196	Gel pressure mattress
E0197	Air pressure pad for mattress, standard mattress length and width
E0198	Water pressure pad for mattress, standard mattress length and width
E0199	Dry pressure pad for mattress, standard mattress length and width
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width

Seat Lift Mechanism

E0627	Seat lift mechanism incorporated into a combination lift-chair mechanism
E0628	Separate seat lift mechanism for use with patient owned furniture–electric
E0629	Separate seat lift mechanism for use with patient owned furniture–non-electric

Transcutaneous Electrical Nerve Stimulator (TENS)

E0720	TENS, two-lead, localized stimulation
E0730	TENS, four-lead, larger area/multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

Power Operated Vehicle (POV)

E1230	Power operated vehicle (three-or four-wheel non-highway).

	Specify brand name and model number

Negative Pressure Wound Therapy (NPWT)

K0538	Negative pressure wound therapy electrical pump, stationary or portable

INFORMATION IN THE PATIENT'S MEDICAL RECORD
The physician has the responsibility to retain information and/or documentation in the patient's medical record which substantiates the patient's medical condition and the need for the items ordered. The DMERC acknowledges that, in some cases, this information will not reside in physician office records, but, rather, in hospital charts, physical therapy progress notes, or SNF records. The DMERC may request this information directly from the physician, institution, or home health provider, in selected cases.

Suppliers and physicians may choose to utilize electronic CMNs (e-CMN). E-CMNs must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

CERTIFICATE OF MEDICAL NECESSITY
For certain items or services billed to a DME Regional Carrier (DMERC), the supplier must receive a signed Certificate of Medical Necessity (CMN) from the treating physician. A supplier must have a faxed or copied original signed order or CMN in their records before they can submit a claim for payment to Medicare. CMNs communicate, either on paper or in an electronic record, required medical necessity information and have a DMERC form number (e.g.,01,02,03) and a revision number (e.g.,.01,.02). Some DMERC forms also have an alpha suffix (e.g., A, B, C). All CMNs have a CMS form number in addition to the DMERC form number. (See the following listing of CMN form numbers.) The CMS form number is in the bottom left corner of the form.

CMNs are referred to by their CMS form numbers. DMERC form numbers identify the CMN on electronic claims submitted to the DMERC in the National Standard Format (NSF). The CMS Form 484 serves as the CMN for home oxygen therapy.

A faxed, copied, original hardcopy, or an electronic CMN must be maintained by the supplier and be available to the DMERCs on request. When hardcopy CMNs are submitted to the DMERC, the supplier must include a copy of only the front side. When CMNs are submitted electronically to the DMERC, only information from sections A, B, and D are required since section C can not be transmitted electronically.

However,suppliers who bill electronically are not exempt from having section C completed on the original CMN.

The following is a list of the currently approved CMNs:

CMN Form Numbers

DMERC Form No.	CMS Form No.	Items Addressed
484.2	484	Home oxygen therapy
01.02A	841	Hospital beds
01.02B	842	Support surfaces
02.03A	843	Motorized wheelchairs
02.03B	844	Manual wheelchairs
03.02O	845	Continuous positive airway pressure (CPAP) devices (This CMN is no longer required for dates of service on or after April 1, 2002.)
04.03B	846	Lymphedema pumps (pneumatic compression devices)
04.03C	847	Osteogenesis stimulators
06.02B	848	Transcutaneous electrical nerve stimulators (TENS)
07.02A	849	Seat lift mechanisms
07.02B	850	Power operated vehicles
09.02O	851	Infusion pumps
10.02A	852	Parenteral nutrition
10.02B	853	Enteral nutrition
11.01	854	Section C continuation (manual and motorized wheelchairs ONLY)

The CMN sent to the physician must be two-sided with instructions on the back. If the CMN is mailed to the physician, the supplier must send the two-sided form. If the CMN is faxed, the supplier must fax both the front and back of the form. It is in the supplier's interest to maintain a copy of what they faxed to the physician. Suppliers must maintain a copy of the completed CMN in their records. However, if the physician only faxes the front of the completed CMN, then the supplier is only required to maintain the front portion of the CMN. Because these forms have been approved by the Office of Management and Budget (OMB), when a CMN is submitted with a paper claim, the hard copy must be an **exact** reproduction of the CMS form.

However, when the CMN is submitted electronically and the supplier chooses to maintain a hard copy CMN,the font may be modified as follows:

- Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- Line spacing must be 6 lines per inch;
- Each CMN must have a minimum ¼-inch margin on all four sides;

Without exception, these modified hard copy forms must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions printed on the back; and CMN question sets may not be combined.

The CMN can serve as the physician's order if the narrative description is sufficiently detailed. This would include quantities needed and frequency of replacement on accessories, supplies, nutrients and drugs. For items requiring a written order prior to delivery (decubitis care items, TENS, POVs, seat lift mechanisms), suppliers may utilize a completed and physician-signed CMN for this purpose. Otherwise, a separate order in addition to a subsequently completed and signed CMN is necessary.

The supplier may not complete the information in section B of the CMN.A supplier who knowingly and willfully completes section B of the form is subject to a civil monetary penalty up to $1,000 for each form or document so distributed. Any supplier who remains in non-compliance after repeated attempts by the contractor to get the supplier into compliance, refer to your RO as a potential civil monetary penalty case.

The information in section C of the CMN (fee schedule amount, narrative description of the items furnished and the supplier's charge for the medical equipment or supplies being furnished) must be completed on the form by the supplier prior to it being furnished to the physician. A supplier who knowingly and willfully fails to include this information may be subject to a civil monetary penalty up to $1,000 for each form or document so distributed. Any supplier who remains in non-compliance, after repeated attempts by the contractor to get the supplier into compliance, refer to your RO as a potential civil monetary penalty case.

Do not modify the language or content when reprinted. Also, do not accept any CMN that has been modified in any way by any other party. In addition, do not accept any other certifications of medical necessity by other insurers or government agencies.

Suppliers and physician may choose to utilize electronic CMNs (e-CMN). E-CMNs must adhere to all privacy, security and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

Completing a CMN

The "Initial Date" found in Section A of the CMN should be either the

specific date that thephysician gives as the start of the medical necessity or, if the physician does not give a specific start date, the "Initial Date " would be the date of the order.

The "Signature Date " is the date the physician signed and dated Section D of the CMN. This date might not be the same as the "Initial Date," since the "Signature Date " must indicate when the physician signed Section D of the CMN.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date " on the CMN or start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within three months from the "Initial Date " of the CMN or three months from the date of the physician's signature.

The DMERCs have the authority to request to verify the information on a CMN at any time. If the information contained either in the supplier's records or in the patient's medical record maintained by the ordering physician fails to substantiate the CMN, or if it appears that the CMN has been altered, the DMERCs should consider the service not reasonable and necessary and initiate the appropriate administrative actions.

In the event of a post pay audit, the supplier must be able to produce the CMN and, if requested by the DMERC, produce information to substantiate the information on the CMN. If the supplier cannot produce this information, the DMERCs should consider the service not reasonable and necessary, and initiate a denial or an overpayment action.

If there is a change made to any section of the CMN after the physician has completed Section B and signed Section D of the CMN, the physician must line through the correction, and initial and date the correction, or the supplier may choose to have the physician complete a new CMN.

CMN as the Written Order

When reviewing claims where the medical record contains a copied, faxed or electronically maintained CMN (any CMN created, modified and stored via electronic means such as commercially available software packages and servers), the DMERC should accept where feasible the copied, faxed or electronic document as fulfilling the requirements for these documents. If evidence indicates that the CMN being reviewed has been falsified, or the supplier is unable to provide adequate assurance of the medical necessity of the items or services, the DMERC can request additional information, including **an original signature**, in order to obtain that assurance.

For items that require a CMN, and for accessories, supplies and drugs related to an item requiring a CMN, the CMN may serve as the detailed written order **IF** the narrative description in Section C is sufficiently detailed (as described above). This applies to both hard copy and electronic orders and CMNs. A supplier must have a hard copied, faxed or electronic

order or CMN in their records before they can submit a claim for payment to Medicare. Suppliers must ensure the security and integrity of electronically maintained CMNs are in accordance with any regulations published by CMS.

Upon request by the DMERCs, suppliers must provide the CMN, in a format that the DMERCs can accept, in a timely manner. Upon medical review, the DMERCs should not deny claims because of the existence of a faxed, copied or electronic order or CMN, unless the document is unreadable or otherwise violates instructions found in Chapter 1 §3.3 of the *Program Integrity Manual* or violates any regulations published by CMS. DMERCs need not make any standard system changes to electronically accept e-CMNs as CMS views e-CMNs as a transaction between the physician and suppliers. The DMERC may request the supplier to download and print a hard copy of an electronic order or CMN if the DMERC cannot access it electronically. Suppliers must continue to use current systems for transmitting claim information to the DMERC.

DMERCs' Authority to Assess an Overpayment and/or Civil Monetary Penalty (CMP) When Invalid CMNs Are Identified

Section 1862(a)(1) of the Act prohibits Medicare payment for services that are not reasonable and necessary. Section 1833(e) of the Act requires that Medicare be furnished by providers and suppliers "such information as may be necessary in order to determine the amount due." These sections provide support that a failure to have a valid CMN on file or to submit a valid CMN to the DMERC makes the underlying claim improper because Medicare does not have sufficient information to determine whether the claim is reasonable and necessary. A valid CMN is one in which the treating physician has attested to and signed supporting the medical need for the item, and the appropriate individuals have completed the medical portion of the CMN. When the DMERCs identify a claim for which a CMN is not valid, they may deny the claim and/or initiate overpayment action.

If a DMERC identifies a supplier that has a pattern of improperly completing the CMN, the DMERC may choose to develop a potential CMP case against the supplier. The authority for such action is found in §1834(j)(2)(A)(iii) of the Act, which states that "any supplier of medical equipment and supplies who knowingly and willfully distributes a CMN in violation of clause (I) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed." The provisions of §1128A of the Act (other than subsections (a) and (b)) shall apply to CMP penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under §1128(A)(a) of the Act.

Expanded Role for Nurse Practitioners/Clinical Nurse Specialists

The Health Care Financing Administration revisited the role of nurse practitioners' and clinical nurse specialists' ability to order durable medical

equipment items and sign the Certificate of Medical Necessity. Section 1861(s)(2)(K)(iii) of the Social Security Act indicates that services which would be physician's services if furnished by a physician, but were rendered by a nurse practitioner or clinical nurse specialist in a rural setting would be considered physician's services if they are authorized to perform such services by the state in which the services are performed and would be covered under the Medicare program. Under the Balanced Budget Act of 1997, the rural setting restriction was removed from this section of the Social Security Act. This revision to the statute is effective for services rendered by nurse practitioners and clinical nurse specialists on or after January 1, 1998.

After considerable review, it is CMS's position that services rendered by a nurse practitioner or clinical nurse specialist working in collaboration with, but independent of, a physician, would be considered covered services, as defined in Section 1861(s)(1) and 1861(s)(2)(A). As a result, under the limitations described in §1861(s)(2)(K)(iii), a nurse practitioner or clinical nurse specialist that is treating the beneficiary is not restricted from ordering DME items or completing Section D on Certificates of Medical Necessity, if they are permitted to do so in the state in which the services are being rendered. Nurse practitioners or clinical nurse specialists must bill using their own provider number and they must attest, the same as the physician, that they have treated the beneficiary and that all information found in Section B is true, accurate and complete, to the best of their knowledge.

Physician Assistant Rules Concerning Orders and CMNs

Physician assistants may provide the dispensing order and write and sign the detailed written order if they satisfy all the following requirements:

- They meet the definition of physician assistant found in §1861(aa)(5)(A) of the Social Security Act and §2156(A) of the *Medicare Carriers Manual*;
- They are treating the beneficiary for the condition for which the item is needed;
- They are practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy;
- They have their own UPIN; and
- They are permitted to perform services in accordance with State law.

Physician assistants may complete Section B and sign Section D of a CMN if they meet all the criteria described above for signing orders.

Physician Coercion by Suppliers

CMNs have two sections that require physician input. Sections B and D have questions concerning the medical condition of the patient, the answers to which guide the DMERC as to the medical necessity of the item being ordered. Section D is for the signature of the physician, attesting not only to

the receipt and accuracy of the information in Sections A and C, but also to the accuracy of the answers in Section B.

The supplier is neither permitted to complete Section B nor tell the physician what answers to give. Suppliers have been known to engage in such activity and even coerce physicians into changing their answers in Section B. Incidentally, Section C of the CMN must be completed by the supplier before the physician signs the document, and should list the charges for the equipment being ordered.

At times, physicians become targets of coercive pressure or harassment by suppliers to justify medical equipment through their orders or CMNs. They are encouraged not to betray their better medical judgement by acquiescing to such pressure, and to report this behavior to the following DMERC contact:

DMERC Program Integrity Department
Provider Hotline
(877) 867-4852

Physicians are also encouraged to request copies of the relevant DMERC medical policies directly from the supplier of the items in question, or they may contact the DMERC Professional Relations department for this material at (803) 763-5744.

Physicians may always discuss aspects of medical policy concerning coverage of this equipment with the DMERC Medical Director, Paul M. Metzger, M.D., at (803) 763-5706.

Legal Responsibility to Complete CMNs

When a physician bills for his/her services, including examination, diagnosis and treatment, any cost associated with paper work is considered part of the charges made for his/her professional services. If a patient needs an item of durable medical equipment orthotics, prosthetics and supplies (DMEPOS), the completion of an order or Certificate of Medical Necessity (CMN) is a service to the patient rather than the supplier. This view is shared by the Health Care Financing Administration and the American Medical Association.

Section 4152 of the Omnibus Reconciliation Act of 1990 requires a physician to complete a CMN or an order for DMEPOS items prescribed. The language in the statute does not authorize physicians to separately charge the patient or supplier for completing the certificates. Allegations of physicians charging suppliers for completing CMNs will be investigated under one or more of the following principles:

- As potential kickback situations under Section 1128B (b) of the Social Security Act; and/or
- As false representation with respect to the physician's actual charge for professional services furnished on or near the date of his/her

DMEPOS order for the beneficiary; and/or
- As a potential assignment violation on assigned claims for professional services on or near the date he/she orders DMEPOS for the beneficiary; or
- As a potential charge limit violation on unassigned claims for professional services on or near the date he/she ordered DMEPOS for the beneficiary.

Cover Letter Guidelines

The Social Security Act was amended in 1994 to specify the types of information suppliers may provide to physicians in a CMN. These types are limited to:

- an identification of the supplier and beneficiary,
- a description of the equipment and supplies being ordered, procedure codes for the equipment and supplies, and
- other administrative information not related to the medical condition of the patient.

It is **not** CMS's or the DMERC's intent to restrict necessary communication between the supplier and the physician. Cover letters can be used as a way for suppliers to communicate with physicians. The information contained in the cover letters should address issues relating to CMS or carrier regulation/policy changes, brief descriptions of the item(s) being provided and changes in the patient regimen.

It **is** CMS's intent to prohibit suppliers from inappropriately influencing the physician's order or instructing the physician regarding what is medically necessary. While suppliers may verify the physician's original order, they may not change the substance of the physician's order or other information furnished by the physician, or add durable medical equipment, prosthetics, orthotics or supply (DMEPOS) items without explicit, documented instructions from the physician.

Providing answers to questions on CMNs or unilaterally changing any aspect of the physician's description of the patient's diagnosis would be considered violation of the statute.

The following are examples of the types of information appropriate to include in cover letters:

- Explanations of the sections of the form the physician must complete (e.g., "complete sections B and D") and/or specific questions the physician must answer;
- Where to send the CMN when they have completed it and how soon they need to do this;
- A copy of test results or report (e.g., blood gas report, wheelchair

evaluation, discharge summary, nurse's notes, etc.) obtained from a hospital, laboratory, outpatient facility, etc.; and
- A direct quote from the Medicare policy (e.g., "A wheelchair is covered if the patient's condition is such that without the use of a wheelchair he/she would otherwise be bed or chair confined.")

Section C of the CMN was designed not only to provide the physician with charge information, but also to function as a confirmation of the physician's order. However, if suppliers wish to duplicate physician order information in a cover letter, they should feel free to do so.

All CMNs must be signed and dated by the ordering physician in Section D. Facsimile stamps are not acceptable. The physician's signature indicates agreement with the information on the CMN. (The physician may not sign a CMN before the information has been entered.) Claims received with CMNs which do not have a valid physician signature will be denied.

CMNs are used primarily for equipment, though at times they may be used to certify accessories/supplies that are used with the equipment.

If a CMN is used, the physician may provide additional narrative information to justify the medical necessity of the item ordered in an individual case. If so, the supplier may include this information along with the CMN.

When the CMN is used, the form sent to the physician for completion/signature should be two-sided, including the instructions on the back. The physician is encouraged though not required to keep a copy of the CMN in the patient's medical record. The supplier must keep the original CMN and/or other documentation provided by the physician in his or her file. A CMN is not required to be maintained in the supplier's files if a prior authorization number has been issued and documented.

On claims filed hard copy, the supplier should send the CMN and/or other documentation with the claim for the purchase or first month's rental. If the CMNs are used, all the information on the CMN can be transmitted electronically using the National Standard Format (NSF). The information on the CMN must be transcribed exactly into the electronic record. If a CMN is not used for documentation, then electronic claim filing would be possible only if the information could fit in the HA0 record of the NSF. Otherwise the claim with the medical necessity/other coverage information would have to be submitted hard copy.

Original CMNs will be audited periodically to validate that they have been completed and transmitted to the DMERC correctly.

Copies of the Certificates of Medical Necessity (CMNs) are included with this Region C DMERC *DMEPOS Supplier Manual.*

Date of Service/Date of Delivery

Medicare law limits Part B payment for durable medical equipment (DME) to that which is used in the patient's home. Hospitals and nursing homes cannot be considered a patient's home for DME purposes.

Generally, for all DME, prosthetics, orthotics and supplies (DMEPOS), the supplier's date of service (DOS) is the date of delivery to a beneficiary's home. For DMEPOS provided to a beneficiary immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the date of final discharge to the beneficiary's home. For mail order DMEPOS provided immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the later of the actual shipping date or the date of discharge. Under no circumstances can the DOS be earlier than the date of delivery, or, in case of mail order DME, the shipping date. In some cases it may be appropriate for DMEPOS suppliers to deliver medically necessary equipment to a facility that does not qualify as the patient's home, up to two days prior to discharge (to a place that does qualify as a home) for the benefit of the patient for purposes of fitting or training of the patient on its use. However, the equipment must be for subsequent use in the beneficiary's home and no billing may be made for this equipment for days used prior to the date of the patient's discharge from the facility to the home. In such cases, the date of discharge is deemed to be the date of delivery. Suppliers are responsible for any necessary delivery of DMEPOS items and cannot bill the beneficiary or the Medicare program for delivery from the facility to the patient's home.

Should a DMEPOS supplier enter into an agreement with such facility to substitute this equipment for DMEPOS required by statute to be provided by the facility, such practice would be considered fraudulent.

Proof of Delivery

Suppliers who bill services/items to the Region C DMERC are required to maintain proof of delivery documentation in the patient's record. The proof of delivery requirements are outlined below according to the method of delivery. The three methods of delivery that will be discussed are:

- Supplier delivering directly to the beneficiary, or authorized representative;
- Supplier utilizing a delivery/shipping service to deliver items; and
- Supplier delivering to a nursing facility on behalf of the beneficiary.

All services which do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently do not provide documentation to support their services may be referred to the Office of Inspector General (OIG) for imposition of Civil Monetary Penalties (CMP) or Administrative Sanctions.

- Supplier delivering items directly to the beneficiary, or authorized representative

A delivery slip which has been signed and dated by the beneficiary, or authorized representative, is required in order to verify the DMEPOS item (s) received. An acceptable delivery slip must include the patient's name, the quantity and detailed description of the item(s) being delivered, brand name and serial number.

- Supplier utilizing a delivery/shipping service to deliver items

If the supplier utilizes a delivery/shipping service, acceptable proof of delivery would include the delivery service's tracking slip and a supplier's shipping invoice. The supplier's shipping invoice must include the patient's name, the quantity and detailed description of the item(s) being delivered, brand name, serial number, and the delivery service's package identification number associated with the patient's package(s). The delivery service's tracking slip must reference each patient's package(s), the delivery address, and the corresponding package identification number given by the delivery service.

When performing compliance audits or developing complaints, the Region C DMERC Fraud Investigation Unit and Medical Review Department request documentation of the claims submitted by the supplier. Often, the documentation returned from the supplier does not include a delivery service log, or only includes a delivery service log which indicates numerous packages were picked up from the supplier. However, the log does not provide the individual package identification number associated with each patient. Without a delivery service's tracking log which identifies each individual package(s) with a unique identification number and the delivery address, the services will be denied and an overpayment will be requested.

Audits have indicated that often packages have been delivered to the wrong address or package(s) have been left at the door or on the porch of the patient's residence. Patients often indicate they did not receive the items/supplies which were shipped by the supplier. In the situations where the patient denies receipt of the items/services, these services will be denied and an overpayment will be requested unless the supplier proves delivery with detailed documentation described above.

Some suppliers have begun the practice of placing a postage-paid delivery invoice in the package(s) delivered to the patient. The patient is then able to sign and date the delivery invoice and mail it back to the supplier to keep in the patient's records to document delivery of the item(s). For mail order DMEPOS item(s), the date of service on the claim must be the shipping date.

- Supplier delivering to a nursing facility on behalf of the beneficiary

Proof of delivery must be maintained in the supplier's records. For patients who are residents of a nursing facility, suppliers should work with the nursing facility staff to implement an inventory control to ensure the following:

- Receipt of the supplies at the nursing facility;
- Supplies are identified and retained for use only by the specific patient for which the supplies/items are intended;
- Supplies are utilized by the patient for which they are issued; and
- Suppliers obtain copies of the necessary documentation from the nursing facility to document the proof of delivery.

The medical records in the nursing home must document the use of all supplies/items billed to Medicare. The documentation may be in the nurse's notes or in a special treatment record or form. The date of service on the claim must be the date the DMEPOS item(s) was received by the nursing facility.

Note: Suppliers are not required to submit proof of delivery with their claims. However, they are expected to retain proof of delivery documentation as described herein to be furnished to the DMERC upon request.

Investigational Devices

On November 1, 1995, Medicare coverage was expanded to include certain medical devices that are being studied as part of a Food and Drug Administration (FDA) trial under Investigational Device Exemptions (IDEs), but have not been approved for marketing. FDA has refined its classification system to distinguish Category A and Category B IDE devices.

Category A IDE devices are experimental and considered to be not medically necessary by Medicare. Category B IDE devices may be covered if all of the following criteria are met:

1. The devices must be used within the context of an FDA-approved clinical trial (i.e., by a beneficiary registered in the trial, within specified dates, through approved institutions, by designated investigators, according to the clinical trial's approved patient protocols, etc.);
2. The device must fall under a covered benefit category and must not be excluded by law, regulation or current *Medicare Carriers Manual* instructions;
3. The device must meet any applicable national or regional policy

criteria; and
4. The device must be reasonable and necessary for the particular patient.

The manufacturer of an item is responsible for notifying the supplier if an item is an FDA-approved IDE device. Effective immediately, if a supplier provides and bills for an FDA-designated IDE device, either category A or B, and if criterion 1 listed above has been met, a QA modifier (FDA Investigational Device Exemption) must be added to the HCPCS code for the item. The supplier must list the FDA-assigned IDE number (one alpha and six numeric digits) in the HA0 record, field 14, of an electronic claim or in box 23 of the CMS-1500 (12-90) claim form. Information documenting that the above coverage criteria have been met does not have to be routinely submitted with the claim, but must be available to the DMERC upon request.

Post-Payment Audits

Post-payment audits are conducted to verify that DMEPOS services billed are covered, medically necessary and reasonable. A supplier's pattern of billing over a period of time may be reviewed by the Medicare Program Integrity Department or the DMERC Medical Review Department to determine any abuse of DMEPOS coverage provisions.

Advance Determination of Medical Coverage (ADMC)

Effective September 1, 2001, prior authorization will no longer be available for power operated vehicles (POVs), seat lift mechanisms, and transcutaneous electrical nerve stimulators (TENS). Prior authorization requests for these items received on or after that date will be returned to the requestor.

Advance Determination of Medicare Coverage (ADMC) is a process by which the DMERC will provide the supplier and beneficiary with a coverage decision prior to delivery of an item. Effective October 1, 2001, an ADMC will be available as an option only for the following wheelchair base HCPCS codes and related options and accessories:

HCPCS Code	Related Options and Accessories
K0005	
K0009	
K0011	only when a power tilt and/or power recline seating system or non-joystick control device (e.g., head control, sip and puff, switch control) is ordered

K0014	only when a power tilt and/or power recline seating system or non-joystick control device (e.g., head control, sip and puff, switch control) is ordered

Note that only a limited subset of K0011 and K0014 wheelchairs (as described above) are eligible for ADMC. When a particular wheelchair base is eligible for ADMC, all wheelchair options and accessories ordered by the physician for that patient along with the base HCPCS code will be eligible for ADMC.

ADMC requests may either be mailed to the DMERC (Palmetto GBA, P.O. Box 100235, Columbia, SC 29202-3235) or faxed to (803) 424-2622. ADMC requests cannot be submitted electronically.

ADMC requests must be accompanied by a copy of the appropriate Certificate(s) of Medical Necessity (CMN)-CMS Form 844 for manual wheelchairs or CMS Form 843 for power wheelchairs, plus CMS Form 854 if more space is needed in Section C to list options and accessories. Completion of the CMN should follow all the standard rules. The manufacturer and model name of the wheelchair base must be listed in Section C. For items billed with HCPCS code K0108 (miscellaneous wheelchair accessory), the narrative in Section C of the CMN must clearly identify the item. (HCPCS code E1399 is not used for wheelchair options or accessories.)

ADMC requests must also be accompanied by information which documents the medical condition of the patient that necessitates the use of the wheelchair, options, and accessories that are ordered. Special attention should be given to any item billed with HCPCS code K0108. Examples (not all-inclusive) of the types of information which will assist the DMERC in making a determination are: the patient's medical records with dated entries; identification of person(s) performing evaluations; date of onset of the condition; strength of the extremities and function of the extremities (including tone, ROM limitations, etc.); the distance that the patient can walk (a) independently and (b) with the assistance of a cane, crutch, or walker; how the patient transfers from bed/chair to a wheelchair; cognitive abilities; visual impairments; current activity level; whether the patient is expected to be fully independent in the use of the wheelchair. Objective measurements should be reported whenever possible.

If the patient currently has a wheelchair or a power operated vehicle (POV), the ADMC request must indicate the reason why it is being replaced.

Upon receipt of an ADMC request, the DMERC will make a determination within 30 calendar days. The DMERC will provide the supplier and beneficiary with its determination, either affirmative or negative, in writing. If it is a negative determination, the letter will indicate why the request was denied—e.g., not medically necessary, insufficient information submitted to determine coverage, statutorily non-covered.

If a wheelchair base receives a negative determination, all accessories will also receive a negative determination. If a wheelchair base receives an affirmative determination, each accessory will receive an individual determination.

An affirmative determination only relates to whether the item is reasonable and necessary based on the information submitted. An affirmative determination does not provide assurance that the beneficiary meets Medicare eligibility requirements nor does it provide assurance that any other Medicare requirements (e.g., place of service, Medicare Secondary Payer) have been met. Only upon submission of a complete claim can the DMERC make a full and complete determination. An affirmative determination does not extend to the price that Medicare will pay for the item. Finally, the DMERC may review selected claims on a pre-payment or post-payment basis and may deny a claim or request an overpayment if it determines that an affirmative determination was made based on incorrect information.

A negative ADMC may not be appealed because it does not meet the regulatory definition of an initial determination since no request for payment is being made. However, if the ADMC request for the wheelchair base is denied and if the supplier obtains additional medical documentation, an ADMC request may be resubmitted. ADMC requests may only be resubmitted once during the six-month period following a negative determination. If the wheelchair base is approved, but one or more accessories are denied, an ADMC request may not be resubmitted for those accessories. If a supplier provides a wheelchair and/or accessories following a negative determination, a claim for the item should be submitted. If new information is provided with the claim, coverage will be considered. If the claim is denied, it may be appealed through the usual process.

An affirmative ADMC is only valid for items delivered within six months following the date of the determination. If the wheelchair is not delivered within that time, the supplier has the option of either submitting a new ADMC request (prior to providing the item) or filing a claim (after providing the item).

If the item is provided within six months following an affirmative determination and if the claim is for all the same items which were listed on the ADMC request, the CMN does not need to be submitted with the claim. If any of the items on the ADMC request were described by HCPCS code K0108 and if those items were provided, the supplier must ensure that the narrative description used on the claim matches the narrative description used on the ADMC determination letter. If a wheelchair base receives an affirmative determination, the supplier may not submit a separate ADMC request for additional accessories. If options or accessories are provided that were not listed on the ADMC request, a revised CMN must be submitted with the claim and the supplier should also submit whatever information is appropriate to document the medical necessity for the new item(s).

NOTE: All reimbursement made for services of non-covered, not medically necessary, or not reasonable items/services will be recouped, unless an Advance Beneficiary Notice is on file.

«BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19-A Intrapulmonary Percussive Ventilation System
.....Chapter 19 - Oxygen
.....Chapter 20 - Nebulizers
.....Chapter 21 - Canes and Crutches
.....Chapter 22 - Walkers
.....Chapter 23 - Commodes
.....Chapter 24 - Manual Wheelchair Base
.....Chapter 25 - Motorized/Power Wheelchair Base
.....Chapter 26 - Wheelchair Options/Accessories
.....Chapter 27 - Power Operated Vehicles (POVs)
.....Chapter 28 - Seat Lift Mechanisms
.....Chapter 29 - Patient Lifts
.....Chapter 30 - Hospital Beds and Accessories
.....Chapter 31 - Reserved for Future Use
.....Chapter 32 - Reserved for Future Use
.....Chapter 33 - Reserved for Future Use
.....Chapter 34 - Reserved for Future Use
.....Chapter 35 - Pressure Reducing Support Surfaces - Group 1
.....Chapter 36 - Pressure Reducing Support Surfaces - Group 2
.....Chapter 37 - Pressure Reducing Support Surfaces - Group 3

DOCUMENTATION REQUIREMENTS

PHYSICIAN ORDERS

Suppliers must have an order from the treating physician before dispensing a DMEPOS item to a beneficiary. Except for items requiring a written order prior to delivery, the dispensing order may be a written, fax or verbal order. The dispensing order must include:

- A description of the item;
- The beneficiary's name;
- The name of the physician; and
- The date of the order.

DETAILED WRITTEN ORDER

A supplier must also have a detailed order in addition to the dispensing order. The supplier must retain the detailed written order and make it available to the DMERC upon request. The detailed order must include:

- Patient's name;
- A description of the item (the description can be either a narrative or a brand name/model number) and the length of need;
- If the order is for accessories or supplies that will be provided on a periodic basis, it must include appropriate information on the quantity used, frequency of change or use, and length of need;
- If the order is a drug, it must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).
- Patient's diagnosis (policy applicable);
- The expected start date of the order;
- The physician's signature and date.

Requirement of New Orders

A new order is required in the following situations:

- There is a change in the order or the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) if specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier/and or physician.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DMERC.

If there is no order (verbal, fax or written) from the doctor upon dispensing, suppliers do not need to file a claim.

WRITTEN ORDERS PRIOR TO DELIVERY

For certain types of durable medical equipment, an order from the physician must be obtained by the supplier prior to delivery of these items. The items subject to this requirement are listed below with the associated HCPCS code. The order must include the patient's full name, a description and the length of

need of the item prescribed, appropriate information on the quantity used, frequency of change or use, and length of need for supplies that will be provided on a periodic basis, the expected start date of the order, and the physician's signature and signature date. The written order should be obtained before delivery and kept in the supplier's records. This requirement applies to these items regardless of the intent by the patient and/or supplier to accept or not accept Medicare assignment.

Items Requiring a Written Order Prior to Delivery

Decubitus Care

A4640	Replacement pad for use with medically necessary alternating pressure pad owned by patient
E0176	Air pressure pad or cushion, non-positioning
E0177	Water pressure pad or cushion, non-positioning
E0178	Gel pressure pad or cushion, non-positioning
E0179	Dry pressure pad or cushion, non-positioning (e.g., eggcrate)
E0180	Pressure pad, alternating, with pump
E0181	Pressure pad, alternating, with pump, heavy duty
E0182	Pump for alternating pressure pad
E0184	Dry pressure mattress
E0185	Gel or gel-like pressure pad for mattress, standard mattress length and width
E0186	Air pressure mattress
E0187	Water pressure mattress
E0192	Low pressure and positioning equalization pad for wheelchair (for example, roho, jay, etc.)
E0193	Powered air flotation bed (low air loss therapy)
E0194	Air-fluidized bed
E0196	Gel pressure mattress
E0197	Air pressure pad for mattress, standard mattress length and width
E0198	Water pressure pad for mattress, standard mattress length and width
E0199	Dry pressure pad for mattress, standard mattress length and width
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width

Seat Lift Mechanism

E0627	Seat lift mechanism incorporated into a combination lift-chair mechanism
E0628	Separate seat lift mechanism for use with patient owned furniture–electric
E0629	Separate seat lift mechanism for use with patient owned furniture–non-electric

Transcutaneous Electrical Nerve Stimulator (TENS)

E0720	TENS, two-lead, localized stimulation
E0730	TENS, four-lead, larger area/multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

DOCUMENTATION REQUIREMENTS

PHYSICIAN ORDERS

Suppliers must have an order from the treating physician before dispensing a DMEPOS item to a beneficiary. Except for items requiring a written order prior to delivery, the dispensing order may be a written, fax or verbal order. The dispensing order must include:

- A description of the item;
- The beneficiary's name;
- The name of the physician; and
- The date of the order.

DETAILED WRITTEN ORDER

A supplier must also have a detailed order in addition to the dispensing order. The supplier must retain the detailed written order and make it available to the DMERC upon request. The detailed order must include:

- Patient's name;
- A description of the item (the description can be either a narrative or a brand name/model number) and the length of need;
- If the order is for accessories or supplies that will be provided on a periodic basis, it must include appropriate information on the quantity used, frequency of change or use, and length of need;
- If the order is a drug, it must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).
- Patient's diagnosis (policy applicable);
- The expected start date of the order;
- The physician's signature and date.

Requirement of New Orders

A new order is required in the following situations:

- There is a change in the order or the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) if specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier and or physician.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DMERC.

WRITTEN ORDERS PRIOR TO DELIVERY

For certain types of durable medical equipment, an order from the physician must be obtained by the supplier prior to delivery of these items. The items subject to this requirement are listed below with the associated HCPCS code. The order must include the patient's full name, a description and the length of need of the item prescribed, appropriate information on the quantity used, frequency of change or use, and length of need for supplies that will be provided on a periodic basis, the expected start date of the order, and the physician's signature and signature date. The written order should be obtained before delivery and

kept in the supplier's records. This requirement applies to these items regardless of the intent by the patient and/or supplier to accept or not accept Medicare assignment.

Items Requiring a Written Order Prior to Delivery

Decubitus Care

A4640	Replacement pad for use with medically necessary alternating pressure pad owned by patient
E0176	Air pressure pad or cushion, non-positioning
E0177	Water pressure pad or cushion, non-positioning
E0178	Gel pressure pad or cushion, non-positioning
E0179	Dry pressure pad or cushion, non-positioning (e.g., eggcrate)
E0180	Pressure pad, alternating, with pump
E0181	Pressure pad, alternating, with pump, heavy duty
E0182	Pump for alternating pressure pad
E0184	Dry pressure mattress
E0185	Gel or gel-like pressure pad for mattress, standard mattress length and width
E0186	Air pressure mattress
E0187	Water pressure mattress
E0192	Low pressure and positioning equalization pad for wheelchair (for example, roho, jay, etc.)
E0193	Powered air flotation bed (low air loss therapy)
E0194	Air-fluidized bed
E0196	Gel pressure mattress
E0197	Air pressure pad for mattress, standard mattress length and width
E0198	Water pressure pad for mattress, standard mattress length and width
E0199	Dry pressure pad for mattress, standard mattress length and width
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width

Seat Lift Mechanism

E0627	Seat lift mechanism incorporated into a combination lift-chair mechanism
E0628	Separate seat lift mechanism for use with patient owned furniture–electric
E0629	Separate seat lift mechanism for use with patient owned furniture–non-electric

Transcutaneous Electrical Nerve Stimulator (TENS)

E0720	TENS, two-lead, localized stimulation
E0730	TENS, four-lead, larger area/multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

<<<BACK

Chapter 8 - Durable Medical Equipment

View Attachments

Click on View Attachments to view the formatted Manual pages regarding durable medical equipment, including repairs, maintenance, replacement, delivery of DME items, and the Six-Point Plan.

DURABLE MEDICAL EQUIPMENT

DME Coverage, Guidelines and Payment Methods

Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits or enables the beneficiary to perform certain tasks that he or she is unable to undertake otherwise due to certain medical conditions and/or illnesses. Durable Medical Equipment includes equipment such as wheelchairs, hospital beds, traction equipment, canes, crutches, walkers, kidney machines, ventilators, oxygen and other medically needed items. DME is considered to be equipment which can withstand repeated use and is primarily and customarily used to serve a medical purpose. It is generally not useful to a person in the absence of an illness or injury and is appropriate for use in the home. There are items, although durable in nature, which may fall into other coverage categories such as braces, prosthetic devices, artificial arms, legs and eyes.

Exceptions

Specified items of equipment may be covered under certain conditions even though they do not meet the definition of Durable Medical Equipment. These items would be covered when it is clearly established that they serve a therapeutic and in some cases preventive purpose. Examples of these items would include gel pads, pressure and water mattresses, and heat lamps. In establishing medical necessity for these type items, the evidence must show that the item is included in the physician's course of treatment and a physician is supervising its use. Payment may also be made under this provision for repairs, maintenance, and delivery of equipment as well as for expendable and nonreusable items essential to the effective use of the equipment.

Medical Necessity
Items classified as DME may not be covered in every instance. Coverage is subject to the requirement that the equipment be necessary and reasonable for the treatment of an illness or injury, or to improve the functioning of a malformed body member. The patient's diagnosis must warrant the type of equipment or supply being purchased or rented. In some instances the physician's prescription and other medical information available to us is sufficient to establish that the equipment or supply is medically necessary. However, there are some DME items that require that a certificate of medical necessity be submitted. The physician's certification must include the patient's diagnosis, the reason equipment is required, and the physician's estimate, in months, of the duration of its need.

Delivery and Service Charges
Delivery and service are an integral part of DMEPOS suppliers' cost of doing business. Such costs are ordinarily assumed to have been taken into account by suppliers (along with all other overhead expenses) in setting the prices they charge for covered items and services. As such, these costs have already been accounted for in the calculation of the fee schedules. Also, most beneficiaries reside in the normal area of business activity of one or more DMEPOS supplier(s) and have reasonable access to them. Therefore, payment for delivery and service charges for DMEPOS is not allowed except in rare and unusual circumstances when the delivery is not typical of the particular supplier's operation.

For example, there may be situations in which it is necessary for a DMEPOS dealer to incur extraordinary delivery expenses in order to meet the needs of beneficiaries living in remote areas that are not served by a local dealer or when a local dealer is temporarily out of stock of required DMEPOS. Medicare may recognize a reasonable separate delivery charge when the supplier must deliver an item of DMEPOS outside its normal area of business activity and the beneficiary does not have access to a supplier whose location is nearer.

When a supplier delivers DMEPOS outside the area in which he normally does business, but the item could have been obtained locally, any separate additional delivery charge may be allowed only to the extent that it does not raise the total payment above the local fee schedule.

When a separate charge can be allowed for delivery/service, the amount is based on mileage and relevant circumstances (submitted with the CMS-1500), including (*Medicare Carriers Manual*, Part 3, §5105):

- the time and distance traveled;
- the actual additional expenses incurred by the supplier;
- the type and quantity of equipment or oxygen delivered;
- customary charge under such circumstances;
- the prevailing charges in the locality under such circumstances; and
- delivery charges made elsewhere in similar localities. Any separate
- delivery charges recognized because of unusual circumstances may,

of course, be paid for only for deliveries that have actually been made

SIX-POINT PLAN

In December 1987, a new law changed the way Medicare reimbursed beneficiaries and suppliers for DME.
DME is classified into six categories. The items in each category are subject to different processing and
payment rules.

1. Inexpensive or Other Routinely Purchased DME (Rent or Purchase)

Inexpensive DME is defined as equipment whose purchase price does not exceed $150. Routinely purchased DME is defined as equipment acquired by purchase at least 75 percent of the time. Equipment in this category can be purchased or rented, however, the total amount paid for monthly rentals cannot exceed the fee schedule purchase amount. Examples include: Canes, walkers, crutches, commode chairs, low pressure and positioning equalization pads, home blood glucose monitors, seat lift mechanisms, pneumatic compressors (lymphedema pumps), portable nebulizers, bed side rails, and traction equipment.

2. Items Requiring Frequent and Substantial Servicing (Rental only)

This category refers to items for which there must be frequent and substantial servicing in order to avoid risk to the patient's health. Examples of these items include ventilators, aspirators, IPPB machines, passive motion exercise devices, etc. Items in this category may be rented for as long as the patient's need continues. However, beginning June 1, 1989, Medicare does not pay for purchased equipment in this category. These items are paid on a monthly rental basis for as long as the patient medically needs the equipment. If the patient purchased an item in this category prior to this date, maintenance is covered if the patient has proof of purchase.

3. General Prosthetic and Orthotic Devices and Supplies, Miscellaneous Supplies and Other Items (Purchase Only)

Prosthetic devices, which replace all or part of an internal body organ, or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ, are covered when furnished on a physician's order. Orthotic devices are items used for the correction or prevention of skeletal deformities. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. Examples of prosthetic devices include items such as Parenteral and Enteral Nutrition (PEN), insertion trays, catheters, drainage bags, skin barriers, lumbar-sacral orthosis (LSO), prostheses (leg, foot, breast, knee, ankle), cardiac pacemakers, prosthetic lenses, maxillofacial devices, and devices which replace all or part of the ear or nose. A urinary collection and retention

system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. Colostomy (and other ostomy) bags and necessary accoutrements required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether or not the attachment of a bag is required. Other miscellaneous supplies are also covered such as sterile saline or water, blood glucose test or reagent strips, lancets, medication, hemodialysis kits, peritoneal dialysis kits, etc. Items in this category may only be purchased.

4. Capped Rental Items (Rent or Purchase)

This category consists of any items not listed in other categories. It includes equipment that costs more than $150.00 and is:

- Not routinely purchased
- Not service intensive
- Not customized
- Not oxygen or oxygen-related

Examples: Hospital beds, wheelchairs, alternating pressure pads, air-fluidized beds, nebulizers with compressor or with compressor or heater, suction pumps, continuous airway pressure (CPAP) devices, patient lifts, and trapeze bars.

For these items of DME, rental payments can be made for up to 15 months. After 15 months, payment can only be made for maintenance and servicing once every six months (beginning six months after the 15th rental payment is made). The item must continue to be provided without charge (other than for the maintenance and servicing fees) until medical necessity ends or Medicare coverage ceases. For this purpose, unless there is a break in need for at least 60 consecutive days, medical necessity is presumed to continue.

After a capped rental item has been rented for three months, the amount of payment is reduced by 25 percent in the fourth month of rental. This reduced allowance is the most that can be allowed for rentals for the remainder of the 15 months.

Once the beneficiary has been renting the item for ten consecutive months (see sample Purchase Option Letter, example #1, page 8.5), Medicare requires the supplier to offer the patient the option of converting their rental agreement to a purchase agreement. If the patient chooses to purchase, Medicare continues to make rental payments for three additional rental months, and the beneficiary then owns the equipment.

If the beneficiary chooses to continue renting, Medicare continues making rental payments for an additional five rental months, for a total of 15 rental payments. After a total of 15 rental payments, the supplier still owns the item. In this case, maintenance and servicing can be paid once every six

months by Medicare to the extent that the charges are reasonable and are not covered by the supplier's or manufacturer's warranty.

The following modifiers must be used when billing capped rental items:

KH	Initial claim, purchase (electric wheelchair) or first month rental
KI	Second or third month rental
KJ	Capped rental, months four to fifteen

A period of continuous use allows for temporary interruptions in the use of equipment. Interruptions may last up to 60 consecutive days PLUS the days remaining in the rental month in which use ceases, regardless of the reason for the interruption. Keep in mind that the rental month may not necessarily mean a "calendar" month because a date of service may run from one month into the next, (i.e., 1/12/1994 to 02/11/1994).

If the interruption is less than 60 consecutive days plus the days remaining in the rental month in which use ceases, we do not begin a new 15 month period. Also when an interruption continues beyond the end of the rental month in which the beneficiary stops using the equipment, we do not make additional rental payments until the beneficiary begins to use the equipment again. We do not count months of interruptions not reimbursed toward the 15 month limit.

If the interruption is greater than 60 consecutive days (plus the days remaining in the rental month in which need ceases) and the supplier submits a new prescription, new medical necessity documentation and a statement describing the reason for the interruption which shows that medical necessity in the prior episode ended, a new 15-month period begins. If the supplier does not submit this documentation, a new 15-month period does not begin (*Medicare Carriers Manual*, Part 3, Section 5102.1.E.3).

If the beneficiary changes to different but similar equipment, the claim must be referred to medical review. If medical review determines that the equipment is medically needed (i.e., the beneficiary's medical needs have substantially changed and the new equipment is necessary), a new 15-month rental period begins with the new equipment. Otherwise, Medicare will reimburse the least expensive piece of equipment (continuing to count against the current 15-month rental period). If the 15-month rental period has already expired, then no additional rental payments can be made.

Claims for capped rental items must be supported by a physician's certification to determine medical necessity and to establish the duration of medical need. Initial claims (both paper and EMC claims) for most capped rental items must be supported by a CMN.

Medicare will pay reasonable and necessary charges for maintenance and servicing of capped rental items. Items in this category are not covered as a

purchase until at least nine months of rental have been covered by Medicare. For purchased equipment, Medicare pays for necessary repairs on an as-needed basis. (See Repairs, Maintenance, Replacement, and Delivery section.)

Please see the sample Purchase Option Letters on pages 8.5 and 8.6. You may photocopy and use these letters as needed.

Electric Wheelchairs (Rent or Purchase)

There are special rules for power-driven wheelchairs which must be offered as a purchase or rental at the time the equipment is furnished. The supplier must notify the carrier (through the use of a modifier) of the beneficiary's decision at the time the initial claim is submitted for processing. No payment can be allowed for rental or purchase services without an indication that the purchase versus rental option was given to the beneficiary. If the beneficiary chooses to purchase the item, reimbursement is made on a lump sum basis. If the beneficiary chooses rental, the purchase option must again be offered by the supplier in the tenth month.

If purchased, the beneficiary is responsible for the 20 percent coinsurance on assigned claims each time the equipment is serviced. However, the beneficiary is responsible for the 20 percent coinsurance and the balance between the Medicare allowed amount and the supplier's charge on non-assigned claims. For equipment that is rented for 15 months, the beneficiary's responsibility for servicing is limited to any deductible applied and the 20 percent coinsurance every six months on the maintenance/servicing payment amount (see sample Purchase Option Letter, example # 2, page 8.6).

Relocation

If the beneficiary moves during or after the 15-month period, either permanently or temporarily, a new rental period does not begin. Responsibility for supplying equipment in the capped-rental category that has been rented for 15 continuous months remains with the supplier who rented the item in the 15th month of the rental period. Responsibility for maintenance and service of the item also remains with that supplier. A move by the Medicare beneficiary does not relieve the supplier who rented the item in the 15th rental month of either responsibility. The responsible supplier may establish an arrangement with a supplier located nearer the beneficiary's new residence to furnish the actual maintenance and service of the equipment.

Beneficiaries Transferring from Medicare HMOs

When a beneficiary who was previously enrolled in a Medicare HMO/Managed Care program returns to traditional fee-for-service Medicare, he is subject to all benefits, rules, requirements and coverage criteria as a beneficiary who has always been enrolled in FFS. When a

beneficiary returns to FFS, it is as though he becomes eligible for Medicare for the first time. Therefore, beneficiaries who received durable medical equipment while on the HMO/Managed Care plan, must qualify for the coverage criteria and documentation requirements under Medicare FFS to continue receiving that item.

For example, if a beneficiary received a manual wheelchair under his HMO/Managed Care plan, he must meet the Medicare DMERC coverage criteria and documentation requirements for manual wheelchairs. An initial CMN would be required and a new rental period would begin.

Exception: Beneficiaries who were previously enrolled in FFS and received a capped rental item, then enrolled in an HMO/Managed Care plan for 60 days or fewer and then returned to FFS. This is a break in service (not a break in medical need) and a new capped rental period does not begin. Medicare FFS continues paying from the last month paid prior to enrollment in the HMO/Managed Care plan.
Another partial exception to this rule involves home oxygen claims, effective for claims received on or after July 1, 2002. If a beneficiary was started on oxygen while in a Medicare HMO, when the beneficiary returns to FFS, the supplier must obtain an initial CMN and submit it to the DMERC at the time that FFS coverage begins. However, the beneficiary does not have to obtain the required blood gas study within 30 days prior to the initial date on the CMN. The test must be the most recent study obtained while the beneficiary was in the HMO, under the guidelines specified in DMERC policy. It is important to note that just because a beneficiary qualified for oxygen under a Medicare HMO, does not mean that s/he will qualify for oxygen under FFS.

These instructions apply whether a beneficiary returns to FFS voluntarily, or involuntarily because their HMO or managed care plan no longer participates in the Medicare+Choice program.

Example 1: Sample Purchase Option Letter - Tenth Month of Rental

Tenth Month Purchase Option Letter for All Capped Rental Items

You have been renting your _____ (specify the item(s) of equipment for 10 continuous months. Medicare requires _____ _____ (specify name of supplier) to give you the option of converting your rental agreement to a purchase agreement. This means that if you accept this option, you would own the medical equipment. If you accept the purchase option, Medicare continues making rental payments for your equipment for 3 additional rental months. You are

responsible for the 20 percent coinsurance amounts or, for unassigned claims, the supplier's entire charge. After these additional rental payments are made, title to the equipment is transferred to you. You have until _____ (specify the date which is one month from the date the supplier notifies the patient of the option) to elect the purchase option. If you decide not to elect the purchase option, Medicare continues making rental payments for an additional 5 rental months, or a total of 15 months. After a total of 15 rental months have been paid, title to the equipment remains with the medical equipment supplier, however, the supplier may not charge you any additional rental amounts.

In making your decision to rent or purchase the equipment, you should know that for purchase equipment, you are responsible for 20 percent of the service charge each time your equipment is actually serviced or, for unassigned claims, the supplier's entire charge. However, for equipment that is rented for 15 months, your responsibility for such service is limited to 20 percent coinsurance on a maintenance and servicing fee payable twice per year when whether or not the equipment is actually serviced.

Supplier's Name

_____

Option Chosen: Purchase [ ] Rental [ ]

Beneficiary's Signature

_____

Date

_____

Example 2: Sample Purchase Option Letter - First Month of Rental

First Month Purchase Option Letter for Electric Wheelchairs

If you need an electric wheelchair prescribed by your doctor, you may already know that Medicare can help pay for it. Medicare requires _____ (specify name of supplier) to give you the option of either renting or purchasing it. If you decide the purchase is more economical, for example, because you will need the electric wheelchair for a long time, Medicare pays 80 percent of the allowed purchase price in a lump sum amount. You are responsible for the 20 percent co-insurance amounts or, for unassigned claims, the suppliers entire charge. However, you must

elect to purchase the electric wheelchair at the time your medical equipment supplier furnishes you with the item. If you elect to rent the electric wheelchair, you are again given the option of purchasing it during your 10th rental month. The option will not be extended at any other time.

If you continue to rent the electric wheelchair for 10 months, Medicare requires _____ _____ (specify name of supplier) to give you the option of converting your rental agreement to a purchase agreement. This means that if you accept this option, you would own the medical equipment. If you accept the purchase option, Medicare continues making rental payments for your equipment for 3 additional rental months. You are responsible for the 20 percent coinsurance amounts or, for unassigned claims, the suppliers entire charge. After these additional rental payments are made, title to the equipment is transferred to you. You have until _____ (specify the date which is one month from the date the supplier notifies the patient of the option) to elect the purchase option. If you decide not to elect the purchase option, Medicare continues making rental payments for an additional 5 rental months, or a total of 15 months. After a total of 15 rental months have been paid, title to the equipment remains with the medical equipment supplier, however, the supplier may not charge you any additional rental amounts.

In making your decision to rent or purchase the equipment, you should know that for purchased equipment, you are responsible for 20 percent of the service charge each time your equipment is actually serviced or, for unassigned claims, the supplier's entire charge. However, for equipment that is rented for 15 months, your responsibility for such service is limited to 20 percent coinsurance on a maintenance and servicing fee payable twice per year whether or not the equipment is actually serviced.

Supplier's Name

_____

Option Chosen: Purchase [ ] Rental [ ]

Beneficiary's Signature

_____

Date

_____

5. Oxygen (Rental Only) and Oxygen Equipment

This category includes stationary and portable gaseous and liquid systems and the oxygen itself. It also contains oxygen concentrators and other oxygen-related equipment. Items in this category may only be rented. Fee

schedule payments for oxygen system rentals are all inclusive and represent a monthly allowance per beneficiary regardless of the amount of oxygen used or the system utilized. An adjustment is made in the monthly fee schedule amounts for extremely high volume or low volume oxygen users. Additional information is presented in a separate chapter on oxygen, Chapter 19 of this manual.

6. Customized Equipment (Including Customized Prosthetic and Orthotic Devices) (Purchase Only)

This category refers to items uniquely constructed or substantially modified to meet the specific needs of an individual patient, (i.e., custom fabrication). This includes those circumstances where an item which has a HCPCS code is modified to the extent that neither the original terminology nor the terminology of another HCPCS code accurately describes the modified term.

This is a one-time purchase category, (i.e., a lump-sum amount is allowed for the purchase). The payment amount for items in this category is individually considered.

REPAIRS, MAINTENANCE, REPLACEMENT AND DELIVERY

Payment may be made for repair, maintenance and replacement of medically required durable medical equipment that the beneficiary owns or is purchasing. This includes equipment that had been in use before the beneficiary enrolled in Medicare Part B.

Maintenance and/or service charges for durable medical equipment covered under a manufacturer or supplier's warranty are not covered unless such charges are excluded from the warranty. In addition, since suppliers usually recover expenses incurred in maintaining equipment in working order from the rental charge, separately itemized charges for repair, maintenance, and the replacement of rented equipment are not covered except in the case of leased dialysis equipment and capped rental items.

Payment is not made for repair, maintenance, and replacement of equipment that requires frequent and substantial servicing, oxygen equipment, and capped rental items that the patient has not elected to purchase. If the beneficiary chooses to continue to rent the item and does not opt to purchase, once the rental cap has been met, payment will not be made for repairs on the capped rental item.

Repairs

Repairs to equipment that a beneficiary is purchasing or already owns are covered when they are necessary in order to make the equipment usable. The repair charge may include the use of "loaner" equipment when this is required. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of

medical need, no payment can be made for the amount in excess.

If a claim is being submitted for labor charges only, the claim should indicate the type of equipment being repaired. All repair claims must indicate that the patient owns the equipment.

Maintenance

Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary's equipment is not covered. However, more extensive maintenance as recommended by the manufacturer and performed by authorized technicians is covered as repairs. This might include breaking down sealed components and performing tests that require specialized testing equipment not available to the beneficiary.
The owner of a capped rental item of DME must provide maintenance and service for it. The penalty for failing to do so is exclusion from the Medicare program. If the owner is no longer in business, the beneficiary may seek the services of any other DME supplier.

In very rare circumstances of malicious damage, culpable neglect, or wrongful disposition, the supplier may document the circumstances and be relieved of the obligation to provide maintenance and service. If a supplier alleges that a beneficiary has maliciously damaged or grossly neglected equipment, Medicare will investigate by examining the evidence and contacting the beneficiary. If it is determined that the damage is malicious or grossly negligent, Medicare will deny additional program payments for Maintenance/Service (MS) as "not reasonable." The beneficiary then becomes liable for repairs and service.

This exception is not a loophole through which suppliers can discharge expensive maintenance and service obligations. The MS payments made are for an average case. Suppliers will make money on some, lose money on others. It is the malicious or negligent act of the beneficiary which relieves the supplier of MS obligations, not the profitability of the maintenance and service contract.

Replacement

Effective May 1, 1991, if a capped rental item of equipment has been in continuous use by the patient, on either a rental or purchase basis, for the equipment's useful lifetime or if the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment. The reasonable useful lifetime for capped rental equipment cannot be less than five years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. If the patient elects to obtain a new piece of equipment, payment is made on a rental or purchase basis, or on a lump-sum purchase basis if a purchase agreement has been entered into initially, (i.e., the patient previously converted a rental agreement to a purchase agreement or purchased an electric wheelchair).

Replacement parts must be billed with the appropriate HCPCS code that represents the item or part being replaced, along with a pricing modifier (NU, UE, RR) and replacement modifier (RP). If you are replacing a part that has not been assigned a specific HCPCS code, use a miscellaneous HCPCS code (E1399 or K0108 for wheelchair parts) to bill each part. Itemization must accompany each claim that contains miscellaneous codes for replacement parts.

The patient can elect to obtain a new piece of capped rental equipment in cases of: loss, irreparable damage, and excessive wear. Expenses for replacement required because of loss or irreparable damage may be reimbursed without a physician's order when in the judgment of the DMERC, the equipment as originally ordered would still satisfy the patient's needs. Medicare will also cover the replacement required due to a change in the patient's condition. In this case, the supplier must include a current physician's order. If medical review determines the equipment is necessary for the patient's condition, a new 15-month rental period begins. If the beneficiary changes suppliers during or after the 15-month rental period, a new rental period does not begin. Payment for the replacement of a capped rental item is subject to the same rules as the initial claim, (i.e., payment for the purchase of an item is permitted only after nine months of rental payments have been made, except power wheelchairs).

Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment will be investigated and denied when the DMERC determines that it would be unreasonable to make program payment under the circumstances. These cases will be referred to the Program Integrity Department.

Delivery

Separate charges for delivery are not normally reimbursed.

Temporary Replacement of Patient-owned Equipment

Effective for claims with dates of service on or after July 1, 1998, HCPCS code **K0462** (Temporary replacement for patient owned equipment being repaired, any type) should be used to bill for the temporary replacement of **beneficiary-owned** equipment which is being repaired.

The monthly allowance of the beneficiary-owned item is payable for one month only, while it is being repaired. This HCPCS code should not be billed and will not be reimbursed for equipment which ahs not been purchased by the beneficiary.

A claim for HCPCS code K0462 must include a narrative description of the equipment being used as a temporary replacement/loan, the manufacturer, brand name, model name or number of the temporary replacement item, and a statement of why the replacement is needed. Claims without this

information will be denied as not medically necessary.

CHANGE OF DME SUPPLIERS

If the beneficiary changes suppliers during or after the 15-month rental period, this does not result in a new rental period. Furthermore, the supplier that provides the item to the beneficiary in the 15th month of the rental period is responsible for supplying the equipment as well as the maintenance and servicing after the 15-month period.

If a DME supplier goes out of business, the supplier retains title to rented equipment. If there is a change in supplier, and if the original supplier does not claim the item from the beneficiary, the beneficiary retains possession but not ownership. If the original supplier takes possession of the capped rental item after 15 months, Medicare cannot pay for the rental or purchase of the item from the new supplier.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Winter 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19 - Oxygen
.....Chapter 20 - Intrapulmonary Percussive Ventilation System
.....Chapter 21 - Nebulizer
.....Chapter 22 - Canes and Crutches
.....Chapter 23 - Walkers
.....Chapter 24 - Commodes
.....Chapter 25 - Manual Wheelchair Base
.....Chapter 26 - Motorized/Power Wheelchair Base

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

«BACK

Chapter 8 - Durable Medical Equipment

View Attachments

Click on View Attachments to view the formatted Manual pages regarding durable medical equipment, including repairs, maintenance, replacement, delivery of DME items, and the Six-Point Plan.

DURABLE MEDICAL EQUIPMENT

DME Coverage, Guidelines and Payment Methods
Durable Medical Equipment (DME) is any equipment that provides therapeutic benefits or enables the beneficiary to perform certain tasks that he or she is unable to undertake otherwise due to certain medical conditions and/or illnesses. Durable Medical Equipment includes equipment such as wheelchairs, hospital beds, traction equipment, canes, crutches, walkers, kidney machines, ventilators, oxygen and other medically needed items. DME is considered to be equipment which can withstand repeated use and is primarily and customarily used to serve a medical purpose. It is generally not useful to a person in the absence of an illness or injury and is appropriate for use in the home. There are items, although durable in nature, which may fall into other coverage categories such as braces, prosthetic devices, artificial arms, legs and eyes.

Exceptions
Specified items of equipment may be covered under certain conditions even though they do not meet the definition of Durable Medical Equipment. These items would be covered when it is clearly established that they serve a therapeutic and in some cases preventive purpose. Examples of these items would include gel pads, pressure and water mattresses, and heat lamps. In establishing medical necessity for these type items, the evidence must show that the item is included in the physician's course of treatment and a physician is supervising its use. Payment may also be made under this provision for repairs, maintenance, and delivery of equipment as well as for expendable and nonreusable items essential to the effective use of the equipment.

Medical Necessity
Items classified as DME may not be covered in every instance. Coverage is subject to the requirement that the equipment be necessary and reasonable for the treatment of an illness or injury, or to improve the functioning of a malformed body member. The patient's diagnosis must warrant the type of equipment or supply being purchased or rented. In some instances the physician's prescription and other medical information available to us is sufficient to establish that the equipment or supply is medically necessary. However, there are some DME items that require that a certificate of medical necessity be submitted. The physician's certification must include the patient's diagnosis, the reason equipment is required, and the physician's estimate, in months, of the duration of its need.

Delivery and Service Charges
Delivery and service are an integral part of DMEPOS suppliers' cost of doing business. Such costs are ordinarily assumed to have been taken into account by suppliers (along with all other overhead expenses) in setting the prices they charge for covered items and services. As such, these costs have already been accounted for in the calculation of the fee schedules. Also, most beneficiaries reside in the normal area of business activity of one or more DMEPOS supplier(s) and have reasonable access to them. Therefore, payment for delivery and service charges for DMEPOS is not allowed except in rare and unusual circumstances when the delivery is not typical of the particular supplier's operation.

For example, there may be situations in which it is necessary for a DMEPOS dealer to incur extraordinary delivery expenses in order to meet the needs of beneficiaries living in remote areas that are not served by a local dealer or when a local dealer is temporarily out of stock of required DMEPOS. Medicare may recognize a reasonable separate delivery charge when the supplier must deliver an item of DMEPOS outside its normal area of business activity and the beneficiary does not have access to a supplier whose location is nearer.

When a supplier delivers DMEPOS outside the area in which he normally does business, but the item could have been obtained locally, any separate additional delivery charge may be allowed only to the extent that it does not raise the total payment above the local fee schedule.

When a separate charge can be allowed for delivery/service, the amount is based on mileage and relevant circumstances (submitted with the CMS-1500), including (*Medicare Carriers Manual*, Part 3, §5105):

- the time and distance traveled;
- the actual additional expenses incurred by the supplier;
- the type and quantity of equipment or oxygen delivered;
- customary charge under such circumstances;
- the prevailing charges in the locality under such circumstances; and
- delivery charges made elsewhere in similar localities. Any separate
- delivery charges recognized because of unusual circumstances may,

of course, be paid for only for deliveries that have actually been made

SIX-POINT PLAN

In December 1987, a new law changed the way Medicare reimbursed beneficiaries and suppliers for DME.
DME is classified into six categories. The items in each category are subject to different processing and
payment rules.

1. Inexpensive or Other Routinely Purchased DME (Rent or Purchase)

Inexpensive DME is defined as equipment whose purchase price does not exceed $150. Routinely purchased DME is defined as equipment acquired by purchase at least 75 percent of the time. Equipment in this category can be purchased or rented, however, the total amount paid for monthly rentals cannot exceed the fee schedule purchase amount. Examples include: Canes, walkers, crutches, commode chairs, low pressure and positioning equalization pads, home blood glucose monitors, seat lift mechanisms, pneumatic compressors (lymphedema pumps), portable nebulizers, bed side rails, and traction equipment.

2. Items Requiring Frequent and Substantial Servicing (Rental only)

This category refers to items for which there must be frequent and substantial servicing in order to avoid risk to the patient's health. Examples of these items include ventilators, aspirators, IPPB machines, passive motion exercise devices, etc. Items in this category may be rented for as long as the patient's need continues. However, beginning June 1, 1989, Medicare does not pay for purchased equipment in this category. These items are paid on a monthly rental basis for as long as the patient medically needs the equipment. If the patient purchased an item in this category prior to this date, maintenance is covered if the patient has proof of purchase.

3. General Prosthetic and Orthotic Devices and Supplies, Miscellaneous Supplies and Other Items (Purchase Only)

Prosthetic devices, which replace all or part of an internal body organ, or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ, are covered when furnished on a physician's order. Orthotic devices are items used for the correction or prevention of skeletal deformities. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. Examples of prosthetic devices include items such as Parenteral and Enteral Nutrition (PEN), insertion trays, catheters, drainage bags, skin barriers, lumbar-sacral orthosis (LSO), prostheses (leg, foot, breast, knee, ankle), cardiac pacemakers, prosthetic lenses, maxillofacial devices, and devices which replace all or part of the ear or nose. A urinary collection and retention

system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. Colostomy (and other ostomy) bags and necessary accoutrements required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether or not the attachment of a bag is required. Other miscellaneous supplies are also covered such as sterile saline or water, blood glucose test or reagent strips, lancets, medication, hemodialysis kits, peritoneal dialysis kits, etc. Items in this category may only be purchased.

4. Capped Rental Items (Rent or Purchase)

This category consists of any items not listed in other categories. It includes equipment that costs more than $150.00 and is:

- Not routinely purchased
- Not service intensive
- Not customized
- Not oxygen or oxygen-related

Examples: Hospital beds, wheelchairs, alternating pressure pads, air-fluidized beds, nebulizers with compressor or with compressor or heater, suction pumps, continuous airway pressure (CPAP) devices, patient lifts, and trapeze bars.

For these items of DME, rental payments can be made for up to 15 months. After 15 months, payment can only be made for maintenance and servicing once every six months (beginning six months after the 15th rental payment is made). The item must continue to be provided without charge (other than for the maintenance and servicing fees) until medical necessity ends or Medicare coverage ceases. For this purpose, unless there is a break in need for at least 60 consecutive days, medical necessity is presumed to continue.

After a capped rental item has been rented for three months, the amount of payment is reduced by 25 percent in the fourth month of rental. This reduced allowance is the most that can be allowed for rentals for the remainder of the 15 months.

Once the beneficiary has been renting the item for ten consecutive months (see sample Purchase Option Letter, example #1, page 8.5), Medicare requires the supplier to offer the patient the option of converting their rental agreement to a purchase agreement. If the patient chooses to purchase, Medicare continues to make rental payments for three additional rental months, and the beneficiary then owns the equipment.

If the beneficiary chooses to continue renting, Medicare continues making rental payments for an additional five rental months, for a total of 15 rental payments. After a total of 15 rental payments, the supplier still owns the item. In this case, maintenance and servicing can be paid once every six

months by Medicare to the extent that the charges are reasonable and are not covered by the supplier's or manufacturer's warranty.

The following modifiers must be used when billing capped rental items:

KH	Initial claim, purchase (electric wheelchair) or first month rental
KI	Second or third month rental
KJ	Capped rental, months four to fifteen

A period of continuous use allows for temporary interruptions in the use of equipment. Interruptions may last up to 60 consecutive days PLUS the days remaining in the rental month in which use ceases, regardless of the reason for the interruption. Keep in mind that the rental month may not necessarily mean a "calendar" month because a date of service may run from one month into the next, (i.e., 1/12/1994 to 02/11/1994).

If the interruption is less than 60 consecutive days plus the days remaining in the rental month in which use ceases, we do not begin a new 15 month period. Also when an interruption continues beyond the end of the rental month in which the beneficiary stops using the equipment, we do not make additional rental payments until the beneficiary begins to use the equipment again. We do not count months of interruptions not reimbursed toward the 15 month limit.

If the interruption is greater than 60 consecutive days (plus the days remaining in the rental month in which need ceases) and the supplier submits a new prescription, new medical necessity documentation and a statement describing the reason for the interruption which shows that medical necessity in the prior episode ended, a new 15-month period begins. If the supplier does not submit this documentation, a new 15-month period does not begin (*Medicare Carriers Manual*, Part 3, Section 5102.1.E.3).

If the beneficiary changes to different but similar equipment, the claim must be referred to medical review. If medical review determines that the equipment is medically needed (i.e., the beneficiary's medical needs have substantially changed and the new equipment is necessary), a new 15-month rental period begins with the new equipment. Otherwise, Medicare will reimburse the least expensive piece of equipment (continuing to count against the current 15-month rental period). If the 15-month rental period has already expired, then no additional rental payments can be made.

Claims for capped rental items must be supported by a physician's certification to determine medical necessity and to establish the duration of medical need. Initial claims (both paper and EMC claims) for most capped rental items must be supported by a CMN.

Medicare will pay reasonable and necessary charges for maintenance and servicing of capped rental items. Items in this category are not covered as a

purchase until at least nine months of rental have been covered by Medicare. For purchased equipment, Medicare pays for necessary repairs on an as-needed basis. (See Repairs, Maintenance, Replacement, and Delivery section.)

Please see the sample Purchase Option Letters on pages 8.5 and 8.6. You may photocopy and use these letters as needed.

Electric Wheelchairs (Rent or Purchase)

There are special rules for power-driven wheelchairs which must be offered as a purchase or rental at the time the equipment is furnished. The supplier must notify the carrier (through the use of a modifier) of the beneficiary's decision at the time the initial claim is submitted for processing. No payment can be allowed for rental or purchase services without an indication that the purchase versus rental option was given to the beneficiary. If the beneficiary chooses to purchase the item, reimbursement is made on a lump sum basis. If the beneficiary chooses rental, the purchase option must again be offered by the supplier in the tenth month.

If purchased, the beneficiary is responsible for the 20 percent coinsurance on assigned claims each time the equipment is serviced. However, the beneficiary is responsible for the 20 percent coinsurance and the balance between the Medicare allowed amount and the supplier's charge on non-assigned claims. For equipment that is rented for 15 months, the beneficiary's responsibility for servicing is limited to any deductible applied and the 20 percent coinsurance every six months on the maintenance/servicing payment amount (see sample Purchase Option Letter, example # 2, page 8.6).

Relocation

If the beneficiary moves during or after the 15-month period, either permanently or temporarily, a new rental period does not begin. Responsibility for supplying equipment in the capped-rental category that has been rented for 15 continuous months remains with the supplier who rented the item in the 15th month of the rental period. Responsibility for maintenance and service of the item also remains with that supplier. A move by the Medicare beneficiary does not relieve the supplier who rented the item in the 15th rental month of either responsibility. The responsible supplier may establish an arrangement with a supplier located nearer the beneficiary's new residence to furnish the actual maintenance and service of the equipment.

Beneficiaries Transferring from Medicare HMOs

When a beneficiary who was previously enrolled in a Medicare HMO/Managed Care program returns to traditional fee-for-service Medicare, he is subject to all benefits, rules, requirements and coverage criteria as a beneficiary who has always been enrolled in FFS. When a

beneficiary returns to FFS, it is as though he becomes eligible for Medicare for the first time. Therefore, beneficiaries who received durable medical equipment while on the HMO/Managed Care plan, must qualify for the coverage criteria and documentation requirements under Medicare FFS to continue receiving that item.

For example, if a beneficiary received a manual wheelchair under his HMO/Managed Care plan, he must meet the Medicare DMERC coverage criteria and documentation requirements for manual wheelchairs. An initial CMN would be required and a new rental period would begin.

Exception: Beneficiaries who were previously enrolled in FFS and received a capped rental item, then enrolled in an HMO/Managed Care plan for 60 days or fewer and then returned to FFS. This is a break in service (not a break in medical need) and a new capped rental period does not begin. Medicare FFS continues paying from the last month paid prior to enrollment in the HMO/Managed Care plan.
Another partial exception to this rule involves home oxygen claims, effective for claims received on or after July 1, 2002. If a beneficiary was started on oxygen while in a Medicare HMO, when the beneficiary returns to FFS, the supplier must obtain an initial CMN and submit it to the DMERC at the time that FFS coverage begins. However, the beneficiary does not have to obtain the required blood gas study within 30 days prior to the initial date on the CMN. The test must be the most recent study obtained while the beneficiary was in the HMO, under the guidelines specified in DMERC policy. It is important to note that just because a beneficiary qualified for oxygen under a Medicare HMO, does not mean that s/he will qualify for oxygen under FFS.

These instructions apply whether a beneficiary returns to FFS voluntarily, or involuntarily because their HMO or managed care plan no longer participates in the Medicare+Choice program.

Example 1: Sample Purchase Option Letter - Tenth Month of Rental

Tenth Month Purchase Option Letter for All Capped Rental Items

You have been renting your
_____ (specify the item(s) of equipment for 10 continuous months. Medicare requires
_____ _____
(specify name of supplier) to give you the option of converting your rental agreement to a purchase agreement. This means that if you accept this option, you would own the medical equipment. If you accept the purchase option, Medicare continues making rental payments for your equipment for 3 additional rental months. You are

responsible for the 20 percent coinsurance amounts or, for unassigned claims, the supplier's entire charge. After these additional rental payments are made, title to the equipment is transferred to you. You have until _____ (specify the date which is one month from the date the supplier notifies the patient of the option) to elect the purchase option. If you decide not to elect the purchase option, Medicare continues making rental payments for an additional 5 rental months, or a total of 15 months. After a total of 15 rental months have been paid, title to the equipment remains with the medical equipment supplier, however, the supplier may not charge you any additional rental amounts.

In making your decision to rent or purchase the equipment, you should know that for purchase equipment, you are responsible for 20 percent of the service charge each time your equipment is actually serviced or, for unassigned claims, the supplier's entire charge. However, for equipment that is rented for 15 months, your responsibility for such service is limited to 20 percent coinsurance on a maintenance and servicing fee payable twice per year when whether or not the equipment is actually serviced.

Supplier's Name

_____

Option Chosen: Purchase [ ] Rental [ ]

Beneficiary's Signature

_____

Date

_____

Example 2: Sample Purchase Option Letter - First Month of Rental

First Month Purchase Option Letter for Electric Wheelchairs

If you need an electric wheelchair prescribed by your doctor, you may already know that Medicare can help pay for it. Medicare requires _____ (specify name of supplier) to give you the option of either renting or purchasing it. If you decide the purchase is more economical, for example, because you will need the electric wheelchair for a long time, Medicare pays 80 percent of the allowed purchase price in a lump sum amount. You are responsible for the 20 percent co-insurance amounts or, for unassigned claims, the suppliers entire charge. However, you must

elect to purchase the electric wheelchair at the time your medical equipment supplier furnishes you with the item. If you elect to rent the electric wheelchair, you are again given the option of purchasing it during your 10th rental month. The option will not be extended at any other time.

If you continue to rent the electric wheelchair for 10 months, Medicare requires _____ _____ (specify name of supplier) to give you the option of converting your rental agreement to a purchase agreement. This means that if you accept this option, you would own the medical equipment. If you accept the purchase option, Medicare continues making rental payments for your equipment for 3 additional rental months. You are responsible for the 20 percent coinsurance amounts or, for unassigned claims, the suppliers entire charge. After these additional rental payments are made, title to the equipment is transferred to you. You have until _____ (specify the date which is one month from the date the supplier notifies the patient of the option) to elect the purchase option. If you decide not to elect the purchase option, Medicare continues making rental payments for an additional 5 rental months, or a total of 15 months. After a total of 15 rental months have been paid, title to the equipment remains with the medical equipment supplier, however, the supplier may not charge you any additional rental amounts.

In making your decision to rent or purchase the equipment, you should know that for purchased equipment, you are responsible for 20 percent of the service charge each time your equipment is actually serviced or, for unassigned claims, the supplier's entire charge. However, for equipment that is rented for 15 months, your responsibility for such service is limited to 20 percent coinsurance on a maintenance and servicing fee payable twice per year whether or not the equipment is actually serviced.

Supplier's Name

_____

Option Chosen: Purchase [ ] Rental [ ]

Beneficiary's Signature

_____

Date

_____

5. Oxygen (Rental Only) and Oxygen Equipment

This category includes stationary and portable gaseous and liquid systems and the oxygen itself. It also contains oxygen concentrators and other oxygen-related equipment. Items in this category may only be rented. Fee

schedule payments for oxygen system rentals are all inclusive and represent a monthly allowance per beneficiary regardless of the amount of oxygen used or the system utilized. An adjustment is made in the monthly fee schedule amounts for extremely high volume or low volume oxygen users. Additional information is presented in a separate chapter on oxygen, Chapter 19 of this manual.

6. Customized Equipment (Including Customized Prosthetic and Orthotic Devices) (Purchase Only)

This category refers to items uniquely constructed or substantially modified to meet the specific needs of an individual patient, (i.e., custom fabrication). This includes those circumstances where an item which has a HCPCS code is modified to the extent that neither the original terminology nor the terminology of another HCPCS code accurately describes the modified term.

This is a one-time purchase category, (i.e., a lump-sum amount is allowed for the purchase). The payment amount for items in this category is individually considered.

REPAIRS, MAINTENANCE, REPLACEMENT AND DELIVERY

Payment may be made for repair, maintenance and replacement of medically required durable medical equipment that the beneficiary owns or is purchasing. This includes equipment that had been in use before the beneficiary enrolled in Medicare Part B.

Maintenance and/or service charges for durable medical equipment covered under a manufacturer or supplier's warranty are not covered unless such charges are excluded from the warranty. In addition, since suppliers usually recover expenses incurred in maintaining equipment in working order from the rental charge, separately itemized charges for repair, maintenance, and the replacement of rented equipment are not covered except in the case of leased dialysis equipment and capped rental items.

Payment is not made for repair, maintenance, and replacement of equipment that requires frequent and substantial servicing, oxygen equipment, and capped rental items that the patient has not elected to purchase. If the beneficiary chooses to continue to rent the item and does not opt to purchase, once the rental cap has been met, payment will not be made for repairs on the capped rental item.

Repairs

Repairs to equipment that a beneficiary is purchasing or already owns are covered when they are necessary in order to make the equipment usable. The repair charge may include the use of "loaner" equipment when this is required. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of

medical need, no payment can be made for the amount in excess.

If a claim is being submitted for labor charges only, the claim should indicate the type of equipment being repaired. All repair claims must indicate that the patient owns the equipment.

Maintenance

Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary's equipment is not covered. However, more extensive maintenance as recommended by the manufacturer and performed by authorized technicians is covered as repairs. This might include breaking down sealed components and performing tests that require specialized testing equipment not available to the beneficiary.
The owner of a capped rental item of DME must provide maintenance and service for it. The penalty for failing to do so is exclusion from the Medicare program. If the owner is no longer in business, the beneficiary may seek the services of any other DME supplier.

In very rare circumstances of malicious damage, culpable neglect, or wrongful disposition, the supplier may document the circumstances and be relieved of the obligation to provide maintenance and service. If a supplier alleges that a beneficiary has maliciously damaged or grossly neglected equipment, Medicare will investigate by examining the evidence and contacting the beneficiary. If it is determined that the damage is malicious or grossly negligent, Medicare will deny additional program payments for Maintenance/Service (MS) as "not reasonable." The beneficiary then becomes liable for repairs and service.

This exception is not a loophole through which suppliers can discharge expensive maintenance and service obligations. The MS payments made are for an average case. Suppliers will make money on some, lose money on others. It is the malicious or negligent act of the beneficiary which relieves the supplier of MS obligations, not the profitability of the maintenance and service contract.

Replacement

Effective May 1, 1991, if a capped rental item of equipment has been in continuous use by the patient, on either a rental or purchase basis, for the equipment's useful lifetime or if the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment. The reasonable useful lifetime for capped rental equipment cannot be less than five years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. If the patient elects to obtain a new piece of equipment, payment is made on a rental or purchase basis, or on a lump-sum purchase basis if a purchase agreement has been entered into initially, (i.e., the patient previously converted a rental agreement to a purchase agreement or purchased an electric wheelchair).

Replacement parts must be billed with the appropriate HCPCS code that represents the item or part being replaced, along with a pricing modifier (NU, UE, RR) and replacement modifier (RP). If you are replacing a part that has not been assigned a specific HCPCS code, use a miscellaneous HCPCS code (E1399 or K0108 for wheelchair parts) to bill each part. Itemization must accompany each claim that contains miscellaneous codes for replacement parts.

The patient can elect to obtain a new piece of capped rental equipment in cases of: loss, irreparable damage, and excessive wear. Expenses for replacement required because of loss or irreparable damage may be reimbursed without a physician's order when in the judgment of the DMERC, the equipment as originally ordered would still satisfy the patient's needs. Medicare will also cover the replacement required due to a change in the patient's condition. In this case, the supplier must include a current physician's order. If medical review determines the equipment is necessary for the patient's condition, a new 15-month rental period begins. If the beneficiary changes suppliers during or after the 15-month rental period, a new rental period does not begin. Payment for the replacement of a capped rental item is subject to the same rules as the initial claim, (i.e., payment for the purchase of an item is permitted only after nine months of rental payments have been made, except power wheelchairs).

Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment will be investigated and denied when the DMERC determines that it would be unreasonable to make program payment under the circumstances. These cases will be referred to the Program Integrity Department.

Delivery

Separate charges for delivery are not normally reimbursed.

Temporary Replacement of Patient-owned Equipment

Effective for claims with dates of service on or after July 1, 1998, HCPCS code **K0462** (Temporary replacement for patient owned equipment being repaired, any type) should be used to bill for the temporary replacement of **beneficiary-owned** equipment which is being repaired.

The monthly allowance of the beneficiary-owned item is payable for one month only, while it is being repaired. This HCPCS code should not be billed and will not be reimbursed for equipment which ahs not been purchased by the beneficiary.

A claim for HCPCS code K0462 must include a narrative description of the equipment being used as a temporary replacement/loan, the manufacturer, brand name, model name or number of the temporary replacement item, and a statement of why the replacement is needed. Claims without this

information will be denied as not medically necessary.

CHANGE OF DME SUPPLIERS

If the beneficiary changes suppliers during or after the 15-month rental period, this does not result in a new rental period. Furthermore, the supplier that provides the item to the beneficiary in the 15th month of the rental period is responsible for supplying the equipment as well as the maintenance and servicing after the 15-month period.

If a DME supplier goes out of business, the supplier retains title to rented equipment. If there is a change in supplier, and if the original supplier does not claim the item from the beneficiary, the beneficiary retains possession but not ownership. If the original supplier takes possession of the capped rental item after 15 months, Medicare cannot pay for the rental or purchase of the item from the new supplier.

«<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19-A Intrapulmonary Percussive Ventilation System
.....Chapter 19 - Oxygen
.....Chapter 20 - Nebulizers
.....Chapter 21 - Canes and Crutches
.....Chapter 22 - Walkers
.....Chapter 23 - Commodes
.....Chapter 24 - Manual Wheelchair Base
.....Chapter 25 - Motorized/Power Wheelchair Base

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<<BACK

Chapter 18 - Medical Policy

View Attachments

This chapter details national policy guidelines for items for which DMERC medical policy does not exist. Click on View Attachments to download and print the entire chapter in PDF format.

Where DMERC Medical Policy Does Not Exist

For DMEPOS items not addressed in a DMERC Medical Policy, the DMERC will apply the National Policy Guidelines in processing claims, when they exist.

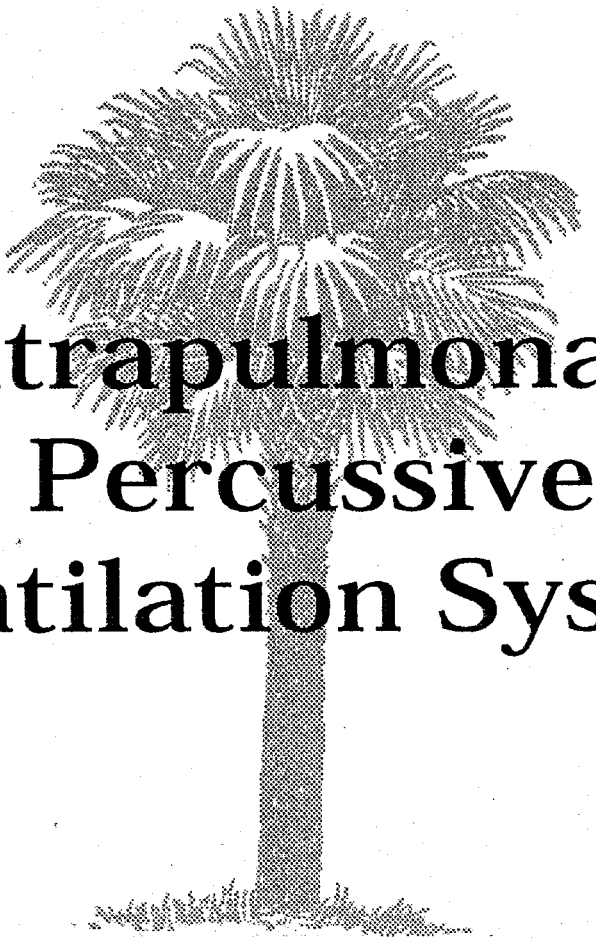
DMERC medical policies are still being developed for the following items or supplies	Conditions according to National Policy Guidelines
Continuous Passive Motion (CPM) Devices	Following total knee replacement within two days of surgery. Coverage limited to three weeks but only while patient is in the home.
IPPB and Fluidic Breathing Assister Nebulizers	Ability to breathe is severely impaired.
Gel flotation pads	Patient has or is highly susceptible to decubitus ulcers, and physician specifies he/she is supervising use and course of treatment.
Fomentation device/heating pads;Hot packs, steam packs	Condition is treated therapeutically by application of heat in the form of a heating pad.
Heat lamps	Condition is treated therapeutically by application of heat in the form of a heating lamp.

Postural Drainage Board	Chronic pulmonary condition
Portable Paraffin Bath Units	Only covered after a successful trial period of paraffin therapy ordered by a physician, and condition is expected to be relieved by long-term use of paraffin therapy.
Respirator/Ventilator	Neuromuscular disease, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Coverage includes both positive and negative pressure types.
Vaporizer	Respiratory illness
Autoclavable urinals	Bed-confined
Ultraviolet Cabinet	Generalized intractable psoriasis, patient must need home treatment.
Whirlpool Bath Equipment	Homebound with condition treated therapeutically by a whirlpool bath.
Sitz Bath	Infection or injury of the perineal area, prescribed by a physician as part of a planned treatment regimen.
Percussor	Chronic obstructive lung disease, chronic bronchitis, emphysema, for mobilizing respiratory tract secretions. Powered percussors are considered when appropriate training has been provided and manual therapy is not an option.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process

CHAPTER 19-A



Intrapulmonary Percussive Ventilation System

REGION C DMERC

DMEPOS SUPPLIER MANUAL

Alabama	*Georgia*	*New Mexico*	*South Carolina*
Arkansas	*Kentucky*	*North Carolina*	*Tennessee*
Colorado	*Louisiana*	*Oklahoma*	*Texas*
Florida	*Mississippi*	*Puerto Rico*	*Virgin Islands*

Contractor Policy Number	IPV
Contractor Name	Palmetto GBA
Contractor Number	00885
Contractor Type	DMERC

RMRP Title

Intrapulmonary Percussive Ventilation System

CMS National Coverage Policy

CIM 60-21

Primary Geographic Jurisdiction

DMERC Region C (Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands)

CMS Region

VI (Dallas), IV (Atlanta), II (New York), VIII (Denver)

CMS Consortia

Southern, Northeast, Western

Original Policy Effective Date

Claims with dates of service on or after July 1, 2002.

Original Policy Ending Date

NA

Revision Effective Date

NA

Revision Ending Date

NA

LMRP Description

An intrapulmonary percussive ventilation system (IPV) delivers a series of pressurized gas minibursts at rates greater than 100 cycles per minute to the respiratory tract.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

An intrapulmonary percussive ventilator (IPV) (E0481) is not covered. These devices have not been demonstrated to be reasonable and necessary in the home setting.

HCPCS Section and Benefit Category

Durable Medical Equipment

HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

E0481	Intrapulmonary pulmonary percussive ventilation system and related accessories.

ICD-9 Codes and Diagnoses that Support Medical Necessity

None

Reasons for Denial

Intrapulmonary percussive ventilation systems will be denied as not medically necessary.

Coding Guidelines

E0481 includes the compressor, hand held units, tubing and all related accessories. This includes both systems in which the minibursts of air are generated by the compressor and systems in which the minibursts of air are generated by a hand held percussive nebulizer used with a standard high-pressure compressor.

Supplier should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §1395l (e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

The supplier must have a signed physician order to submit a claim to Medicare.

Utilization Guidelines

NA

Sources of Information and Basis for Decision

CMS National Coverage Determination (CIM 60-21) Intrapulmonary Percussive Ventilation (IPV) not covered

Advisory Committee Notes

NA

Start Date of Comment Period

NA

End Date of Comment Period

NA

Start Date of Notice Period

Revision History

NA

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

«BACK

Chapter 19-A Intrapulmonary Percussive Ventilation System

View Attachments

Contractor Policy Number IPV
Contractor Name Palmetto GBA
Contractor Number 00885
Contractor Type DMERC

RMRP Title

Intrapulmonary Percussive Ventilation System

CMS National Coverage Policy

CIM 60-21

Primary Geographic Jurisdiction

DMERC Region C (Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands)

CMS Region

VI (Dallas), IV (Atlanta), II (New York), VIII (Denver)

CMS Consortia

Southern, Northeast, Western

Original Policy Effective Date

Claims with dates of service on or after July 1, 2002.

Original Policy Ending Date

NA

Revision Effective Date

NA

Revision Ending Date

NA

LMRP Description

An intrapulmonary percussive ventilation system (IPV) delivers a series of pressurized gas minibursts at rates greater than 100 cycles per minute to the respiratory tract.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

An intrapulmonary percussive ventilator (IPV) (E0481) is not covered. These devices have not been demonstrated to be reasonable and necessary in the home setting.

HCPCS Section and Benefit Category

Durable Medical Equipment

HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

E0481 Intrapulmonary pulmonary percussive ventilation system and related accessories.

ICD-9 Codes and Diagnoses that Support Medical Necessity

None

Reasons for Denial

Intrapulmonary percussive ventilation systems will be denied as not medically necessary.

Coding Guidelines

E0481 includes the compressor, hand held units, tubing and all related accessories. This includes both systems in which the minibursts of air are generated by the compressor and systems in which the minibursts of air are generated by a hand held percussive nebulizer used with a standard high-pressure compressor.

Supplier should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951 (e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

The supplier must have a signed physician order to submit a claim to Medicare.

Utilization Guidelines

NA

Sources of Information and Basis for Decision

CMS National Coverage Determination (CIM 60-21) Intrapulmonary Percussive Ventilation (IPV) not covered

Advisory Committee Notes

NA

Start Date of Comment Period

NA

End Date of Comment Period

NA

Start Date of Notice Period

Revision History

NA

<<<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19-A Intrapulmonary Percussive Ventilation System
.....Chapter 19 - Oxygen

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<<BACK

Chapter 19 - Oxygen

View Attachments

Chapter 19 contains the oxygen medical policy. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Oxygen and Oxygen Equipment

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

Equipment:

E0424	Stationary compressed gaseous oxygen system, rental; includes contents (per unit), regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing; 1 unit = 50 cubic ft.
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor
E0439	Stationary liquid oxygen system, rental; includes use of

	reservoir, contents (per unit), regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing; 1 unit = 10 lbs.
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous, per unit (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned; 1 unit = 50 cubic ft.)
E0442	Oxygen contents, liquid, per unit (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned; 1 unit = 10 lbs.)
E0443	Portable oxygen contents, gaseous, per unit (for use only with portable gaseous systems when no stationary gas or liquid system is used; 1 unit = 5 cubic ft.)
E0444	Portable oxygen contents, liquid, per unit (for use only with portable liquid systems when no stationary gas or liquid system is used; 1 unit = 1 lb.)
E1390	Oxygen concentrator, capable of delivering 85% or greater oxygen concentration at the prescribed flow rate

Accessories:

A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouthpiece
A4619	Face tent
A4620	Variable concentration mask
A4621	Tracheostomy mask or collar
A9900	Miscellaneous supply, accessory and/or service component of another HCPCS code
E0455	Oxygen tent, excluding croup or pediatric tents
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1353	Regulator
E1355	Stand/rack

HCPCS MODIFIERS:

QE	Prescribed amount of oxygen is less than 1 liter per minute (LPM)
QF	Prescribed amount of oxygen is greater than 4 liters per minute

	(LPM) and portable oxygen is also prescribed
QG	Prescribed amount of oxygen is greater than 4 liters per minute (LPM) and portable oxygen is not prescribed
QH	Oxygen conserving device is being used with an oxygen delivery system

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 60-4

DEFINITION:
The term blood gas study in this policy refers to either an arterial blood gas (ABG) test or an oximetry test. An ABG is the direct measurement of the partial pressure of oxygen (PO_2) on a sample of arterial blood. The PO_2 is reported as mm Hg. An oximetry test is the indirect measurement of arterial oxygen saturation using a sensor on the ear or finger. The saturation is reported as a percent.

COVERAGE AND PAYMENT RULES:
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

Home oxygen therapy is covered only if all of the following conditions are met:

1. The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and

2. The patient's blood gas study meets the criteria stated below, and

3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and

4. The qualifying blood gas study was obtained under the following conditions:
   - If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than two days prior to the hospital discharge date, or
   - If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the patient is in a chronic stable state -- i.e., not during a

period of acute illness or an exacerbation of their underlying disease, and

5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

Group I criteria include any of the following:

1. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or

2. An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% while awake, or

3. A decrease in arterial PO_2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent taken during sleep associated with symptoms or signs reasonably attributable to hypoxemia (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis), or

4. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

Initial coverage for patients meeting Group I criteria is limited to 12 months or the physician-specified length of need, whichever is shorter. (Refer to the Documentation section for information on recertification.)

Group II criteria include the presence of (a) an arterial PO_2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep, or during exercise (as described under Group I criteria) and (b) any of the following:

1. Dependent edema suggesting congestive heart failure, or

2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than three mm in standard leads II, III, or AVF), or

3. Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for patients meeting Group II criteria is limited to three months or the physician specified length of need, whichever is shorter. (Refer to the Documentation section for information on recertification.)

Group III includes patients with arterial PO2 levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these patients there is a rebuttable presumption of noncoverage.

If all of the coverage conditions specified above are not met, the oxygen therapy will be denied as not medically necessary. Oxygen therapy will also be denied as not medically necessary if any of the following conditions are present:

1. Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood and there are other preferred treatments.

2. Dyspnea without cor pulmonale or evidence of hypoxemia.

3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO_2 will improve the oxygenation of tissues with impaired circulation.

4. Terminal illnesses that do not affect the respiratory system.

The qualifying blood gas study must be performed by a physician or by a qualified Medicare Part A provider or a qualified laboratory. A supplier is not considered a qualified provider or a qualified laboratory for purposes of this policy. In addition, the qualifying blood gas study may not be paid for by any supplier. This prohibition does not extend to blood gas studies performed by a hospital certified to do such tests.

The qualifying blood gas study may be performed while the patient is on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

For Initial Certifications, the blood gas study reported on the Certificate of Medical Necessity (CMN) must be the most recent study obtained prior to the Initial Date indicated in Section A of the CMN and this study must be obtained within 30 days prior to that Initial Date.

For patients initially meeting Group I criteria, the most recent blood gas study prior to the thirteenth month of therapy must be reported on the Recertification CMN. For patients initially meeting Group I criteria, if the estimated length of need on the Initial CMN is less than lifetime and the

physician wants to extend coverage, a repeat blood gas study must be performed within 30 days prior to the date of the Revised Certification.

For patients initially meeting Group II criteria, the most recent blood gas study which was performed between the 61st and 90th day following Initial Certification must be reported on the Recertification CMN. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy, but the patient continues to use oxygen and a test is obtained at a later date, if that test meets Group I or II criteria, coverage would resume beginning with the date of that test. For patients initially meeting Group II criteria, if the estimated length of need on the Initial CMN is less than lifetime and the physician wants to extend coverage, a repeat blood gas study must be performed within 30 days prior to the date of the Revised Certification.

For any Revised CMN, the blood gas study reported on the CMN must be the most recent test performed prior to the Revised date.

A repeat blood gas study may be requested at any time at the discretion of the DMERC.

When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), only report the ABG PO_2 on the CMN. If the ABG PO_2 result is not a qualifying value, home oxygen therapy will be denied as not medically necessary, regardless of the oximetry test result.

Portable Oxygen Systems:
A portable oxygen system is covered if the patient is mobile within the home and the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not medically necessary.

If coverage criteria are met, a portable oxygen system is usually separately payable in addition to the stationary system. (See exception in Liter Flow Greater Than 4 LPM.)

Liter Flow Greater Than 4 LPM:
If basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow rate of greater than 4 liters per minute (LPM) will be paid only if a blood gas study performed while the patient is on 4 LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance.

If a patient qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, payment will be made for either the stationary system (at the higher allowance) or the portable system (at the standard fee schedule allowance for a portable system), but not both. In this situation, if both a stationary system and a

portable system are billed for the same rental month, the portable oxygen system will be denied as not separately payable.

Oxygen Contents:
Oxygen contents are included in the allowance for rented oxygen systems. Stationary oxygen contents (E0441, E0442) are separately payable only when the coverage criteria for home oxygen have been met and they are used with a patient owned stationary gaseous or liquid system respectively. Portable contents (E0443, E0444) are separately payable only when the coverage criteria for home oxygen have been met and:

a. the beneficiary owns a concentrator and rents or owns a portable system, or
b. the beneficiary rents or owns a portable system and has no stationary system (concentrator, gaseous, or liquid).

If the criteria for separate payment of contents are met, they are separately payable regardless of the date that the stationary or portable system was purchased.

Oxygen Accessories:
Accessories, including but not limited to, cannulas (A4615), humidifiers (E0555), masks (A4620, A4621), mouthpieces (A4617), nebulizer for humidification (E0580), oxygen conserving devices (A9900), regulators (E1353), transtracheal catheters (A9900), and tubing (A4616) are included in the allowance for rented systems. The supplier must provide any accessory ordered by the physician. Accessories are separately payable only when they are used with a patient-owned system that was purchased prior to June 1, 1989. Accessories used with a patient-owned system that was purchased on or after June 1, 1989 will be denied as noncovered.

Travel Oxygen:
If a beneficiary travels out of their supplier's usual service area, it is the beneficiary's responsibility to arrange for oxygen during their travels. Medicare will only pay one supplier for oxygen during any one rental month.

Oxygen services furnished by an airline to a beneficiary are noncovered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier.

Miscellaneous:
The patient must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification. The patient must be seen and re-evaluated by the treating physician within 90 days prior to the date of any Recertification.

Only rented oxygen systems (E0424, E0431, E0434, E0439, E1390RR) are eligible for coverage. Purchased oxygen systems (E0425, E0430, E0435,

E0440, E1390NU, E1390UE) will be denied as noncovered.

Emergency or stand-by oxygen systems will be denied as not medically necessary since they are precautionary and not therapeutic in nature.

Respiratory therapists' services are noncovered under the DME benefit.

CODING GUIDELINES:
For gaseous or liquid oxygen systems or contents, report one unit of service for one month rental. Do not report in cubic feet or pounds.

The appropriate modifier must be used if the prescribed flow rate is less than 1 LPM (QE) or greater than 4 LPM (QF or QG). These modifiers may only be used with stationary gaseous (E0424) or liquid (E0439) systems or with an oxygen concentrator (E1390). They must not be used with codes for portable systems or oxygen contents.

Claims for oxygen contents and/or oxygen accessories should not be submitted in situations in which they are not separately payable (see above).

Code ZZ010 (Transtracheal oxygen catheter for patient-owned equipment) is invalid for claim submission to the DMERC.

Codes E1405 and E1406 (Oxygen and water vapor enriching system) are invalid for claim submission to the DMERC. Codes E1377-E1385 (Oxygen concentrator, high humidity system) are invalid for claim submission to the DMERC.

DOCUMENTATION:
For an item(s) to be considered for coverage and payment by Medicare, the information submitted by the supplier must be corroborated by documentation in the patient's medical records that Medicare coverage criteria have been met. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, or records from other healthcare professionals. This documentation must be available to the DMERC upon request.

An order for the oxygen system and all related accessories which has been signed and dated by the treating physician must be kept on file by the supplier. A certificate of medical necessity (CMN) which has been signed and dated by the treating physician must be kept on file by the supplier. The CMN for home oxygen is HCFA Form 484. If the information on the CMN is sufficiently detailed, it may be used as an order. In addition to the order information that the physician enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the oxygen order or the physician can enter the other details directly--e.g., the means of oxygen delivery (cannula, mask, etc.) and the specifics of varying oxygen flow rates and/or noncontinuous use of oxygen.

If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GX0, GX1, and GX2 records. (See DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it should be transcribed into the HAØ record. If a hard copy claim is submitted, a copy of the CMN must be attached.

An Initial, Recertification, or Revised CMN must be submitted to the DMERC in the situations described below. The Initial Date, Recertification Date, and Revised Date specified below refer to the dates reported in Section A of the CMN.

Initial CMN is Required:

- With the first claim to the DMERC for home oxygen (even if the patient was on oxygen prior to Medicare eligibility or was initially covered by a Medicare HMO).
- When there has been a change in the patient's condition that has caused a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the need for oxygen ended. (This indication does not apply if there was just a break in billing because the patient was in a hospital, nursing facility, hospice, or Medicare HMO, but the patient continued to need oxygen during that time.)
- When the patient initially qualified in Group II, repeat blood gas studies were not performed between the 61st and 90th day of coverage, but a qualifying study was subsequently performed. The Initial Date on this new CMN may not be any earlier than the date of the subsequent qualifying blood gas study.

The blood gas study reported on the Initial CMN must be the most recent study obtained prior to the Initial Date and this study must be obtained within 30 days prior to that Initial Date.

Recertification CMN is Required:

- Three months after Initial Certification (i.e., with the fourth month's claim) - if oxygen test results on the Initial Certification are in Group II. The blood gas study reported must be the most recent study which was performed between the 61st and 90th day following the Initial Date.
- 12 months after Initial Certification (i.e., with the thirteenth month's claim) - if oxygen test results on the Initial Certification are in Group I. The blood gas study reported must be the most recent blood gas study prior to the thirteenth month of therapy.
- In other situations at the discretion of the DMERC. The blood gas study reported must be the most recent study which was performed within 30 days prior to the Recertification Date.

Revised CMN is Required:

- When the prescribed maximum flow rate changes from one of the following categories to another: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM. If the change is from category (a) or (b) to category (c), a repeat blood gas study with the patient on 4 LPM must be performed within 30 days prior to the start of the greater than 4 LPM flow.
- When a portable oxygen system is added subsequent to Initial Certification of a stationary system. In this situation, there is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the patient is at rest (awake) or during exercise within 30 days prior to the Revised Date.
- When the length of need expires -- if the physician specified less than lifetime length of need on the most recent CMN. In this situation, a revised blood gas study must be performed within 30 days prior to the Revised Date.
- When there is a new treating physician but the oxygen order is the same. In this situation, there is no requirement for a repeat blood gas study. Note: In this situation, the Revised CMN does not have to be submitted with the claim but must be kept on file by the supplier.

If there is a new supplier, that supplier must be able to provide the DMERC with an original CMN on request. (An original CMN is a CMN which has a physician's original signature on it. It is not necessarily an Initial CMN or the first CMN for that patient.) If the supplier obtains a new CMN, it would be considered a Revised CMN. In this situation, if the oxygen order is the same, the CMN does not have to be submitted with the claim.

Submission of a Revised CMN does not change the Recertification schedule specified above.

If the indications for a Revised CMN are met at the same time that a Recertification CMN is due, file the CMN as a Recertification CMN.

Miscellaneous:
In the following situations, a new order must be obtained and kept on file by the supplier, but neither a new CMN nor a repeat blood gas study are required:

- Prescribed maximum flow rate changes but remains within one of the following categories: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM.
- Change from one type of system to another (i.e., concentrator, liquid, gaseous).

Refer to the Supplier Manual for more information on orders, Certificates of

Medical Necessity, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2000.

This is a revision of a previously published policy.

NOTE: Measurement of oxygen saturation in the capillary blood using an oximeter is an option for documenting medical necessity of home oxygen and respiratory assist devices. Suppliers are reminded that in order to be considered acceptable documentation, this test must be performed by a Medicare-approved provider.

> *A Medicare-approved provider may be a physician, hospital, nursing facility, home health agency, laboratory, or independent diagnostic testing facility (IDTF) that is enrolled with a local carrier, local intermediary, or regional home health intermediary (RHHI). Entities that just perform the technical component of a test (e.g., providing the oximeter for home sleep studies) which is then purchased by a physician and billed by the physician to the local carrier must also be an enrolled Medicare provider — even though they will not bill Medicare directly.*
>
> *In addition, in order to be considered acceptable documentation, the test may not be performed by a DMEPOS supplier or anyone financially associated with or related to the supplier*

NOTE:
OXYGEN BILLING TIPS
The following chart has been provided as a quick reference to help suppliers determine what oxygen items may be billed separately.

If Type of System Is:	Can Stationary Equipment Be Billed?	Can Stationary Contents Be Billed?	Can Portable Equipment Be Billed?	Can Portable Contents Be Billed?
A. Situation: Beneficiary Uses a Stationary System Only:				
1. Rents Stationary System				
Concentrator	Yes	No	No	No
Gaseous	Yes	No	No	No
Liquid	Yes	No	No	No
2. Owns Stationary System				
Concentrator	No	No	No	No
Gaseous	No	Yes	No	No

Liquid	No	Yes	No	No
B. Situation: Beneficiary Uses Both a Stationary and a Portable				
1. Rents Stationary/Rents Portable				
Concentrator	Yes	No	Yes	No
Gaseous	Yes	No	Yes	No
Liquid	Yes	No	Yes	No
2. Rents Stationary/Owns Portable				
Concentrator	Yes	No	No	No
Gaseous	Yes	No	No	No
Liquid	Yes	No	No	No
3. Owns Stationary/Owns Portable				
Concentrator	No	No	No	Yes
Gaseous	No	Yes	No	No
Liquid	No	Yes	No	No
4. Owns Stationary/Rents Portable				
Concentrator	No	No	Yes	Yes
Gaseous	No	Yes	Yes	No
Liquid	No	Yes	Yes	No
C. Situation: Beneficiary Uses a Portable System Only				
1. Rents Portable System				
Gaseous	No	No	Yes	Yes
Liquid	No	No	Yes	Yes
2. Owns Portable System				
Gaseous	No	No	No	Yes
Liquid	No	No	No	Yes

To download a printable version of the Certificate of Medical Necessity for oxygen (DMERC 484.2; HCFA-484), click on View Attachments above.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Winter 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse

HCPCS MODIFIERS

KO	Single drug unit dose formulation
KP	First drug of a multiple drug unit dose formulation
KQ	Second or subsequent drug of a multiple drug unit dose formulation

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issue Manual 60-9

DEFINITIONS

Equipment

In this policy, the actual equipment (i.e., electrical device) will generally be referred to as either a compressor (when nebulization of liquid is achieved by means of air flow) or as a generator (when nebulization of liquid is achieved by means of ultrasonic vibrations). The term nebulizer is generally used for the actual chamber in which the nebulization of liquid occurs and is an accessory to the equipment. The nebulizer is attached to an aerosol compressor or an ultrasonic generator in order to achieve a functioning delivery system for aerosol therapy.

Code E0565 describes an aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m and is capable of continuous operation.

A nebulizer with compressor (E0570) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It is only AC powered.

A portable compressor (E0571) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It must have battery or DC power capability and may have an AC power option.

A light duty adjustable pressure compressor (E0572) is a pneumatic aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m, but is capable only of intermittent operation.

Code E0574 describes an ultrasonic generator used with a small volume chamber for medication delivery which is capable only of intermittent operation.

Code E0575 describes a large volume ultrasonic nebulizer system which is used for medication and humidification delivery, and which is capable of continuous operation.

Accessories

Code A7003, A7005, and A7006 include the lid, jar, baffles, tubing, T-piece and mouthpiece. In addition, code A7006 includes a filter.

Code A7004 includes only the lid, jar and baffles.

Code A7012 describes a device to collect water condensation which is placed in line with the corrugated tubing used with a large volume nebulizer.

Inhalation Drugs

Unit dose form of an inhalation drug or a combination of drugs is one in which the medication is dispensed to a patient (1) in a bottle/vial/ampule which contains the dose usually used for a single inhalation

treatment, and (2) in a concentration which is dilute enough that it may be administered to a patient ithout adding any separate diluent.

Concentrated form of a drug used for inhalation is one in which the drug is dispensed to a patient in a concentration which requires that a separate diluent (usually saline) be added to the nebulizer when the drug is administered to a patient.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) fit into a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

A small volume nebulizer (A7003, A7004, A7005) and related compressor (E0570, E0575) are covered when:

a) It is medically necessary to administer beta-adrenergics, anticholinergics, corticosteroids, and cromolyn for the management of obstructive pulmonary disease (ICD-9 diagnosis codes 491.0 - 505), or
b) It is medically necessary to administer gentamicin, tobramycin, amikacin, or dornase alfa to a patient with cystic fibrosis (ICD-9 diagnosis code 277.00) or
c) It is medically necessary to administer pentamidine to patients with HIV (ICD-9 code 042), pneumocystosis (ICD-9 diagnosis code 136.3), and complications of organ transplants (ICD-9 diagnosis codes 996.8-996.89), or
d) It is medically necessary to administer mucolytics (other than dornase alpha) for persistent thick or tenacious pulmonary secretions (ICD-9 diagnosis code 786.4).

Use of inhalation drugs, other than those listed above, will be denied as not medically necessary.

For criterion (a) to be met, the physician must have considered use of a metered dose inhaler (MDI) with and without a reservoir or spacer device and decided that, for medical reasons, it was not sufficient for the administration of needed inhalation drugs. The reason for requiring a small volume nebulizer and related compressor/generator instead of or in addition to an MDI must be documented in the patient's medical record and be available to the DMERC on request.

If none of the drugs used with a nebulizer are covered, the nebulizer and its accessories/supplies will be denied as not medically necessary.

A large volume nebulizer (A7017), related compressor (E0565 or E0572), and water or saline (K0182 or K0529) are covered when it is medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis (ICD-9 diagnosis code 277.00), bronchiectasis (ICD-9 diagnosis code 494 or 748.61), or a tracheostomy (ICD-9 diagnosis code V44.0 or V55.0), or a tracheobronchial stent (ICD-9 diagnosis code 519.1). Combination code E0585 will be covered for the same indications. An E0565 or E0572 compressor and filtered nebulizer (A7006) are also covered when it is medically necessary to administer pentamidine to patients with HIV (ICD-9 diagnosis code 042). If a large volume nebulizer, related compressor/generator, and water or saline are used predominantly to provide room humidification it will be denied as noncovered.

Because there is no proven medical benefit to nebulizing particles to diameters smaller than achievable with a pneumatic model, when a small volume ultrasonic nebulizer (E0574) is ordered, it will be reimbursed at the least costly alternative of a pneumatic compressor (E0570).

Similarly, a large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor. However, since code E0575 is in a different payment category than pneumatic compressors,

payment for a least costly alternate cannot be made. Therefore, when an E0575 nebulizer is provided, it will be denied as not medically necessary as will any related accessories and supplies.

A battery powered compressor (E0575) is rarely medically necessary. If this compressor is provided without accompanying documentation which justifies its medical necessity, and the coverage criteria for code E0570 are met, payment will be based on the allowance for the least costly medically acceptable alternative, E0570.

Other uses of compressors/generators will be considered individually on a case by case basis, to determine their medical necessity.

Accessories:

A large volume pneumatic nebulizer (E0580) and water or saline (A7018 or A7020) are not separately payable and should not be separately billed when used for patients with rented home oxygen equipment.

Disposable large volume nebulizers (A7007 and A7008) are noncovered under the DME benefit because they are convenience items. A non-disposable unfilled nebulizer (A7017 or E0585) filled with water or saline (A7018, A7020) by the patient/caregiver is an acceptable alternative.

Kits and concentrates for use in cleaning respiratory equipment will be denied as noncovered.

Accessories are separately payable if the related aerosol compressor and the individual accessories are medically necessary. The following table lists the compressor/generator which is related to the accessories described. Other compressor/generator/accessory combinations are considered medically unnecessary.

COMPRESSOR/GENERATOR	RELATED ACCESSORIES
E0565	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015, A7017, E1372
E0570	A4621, A7003, A7004, A7005, A7006, A7013, A7015
E0585	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015
E0572	A7006, A7014
E0574	A7014, A7016
E0575	A4621, A7003, A7004, A7005, A7006, A7013, A7015

This array of accessories represents all possible combinations but it may not be appropriate to bill any or all of them for one device.

The following table lists the usual maximum frequency of replacement for accessories. Claims for more than the usual maximum replacement amount will be denied as not medically necessary unless the claim is accompanied by documentation which justifies a larger quantity in the individual case.

ACCESSORY	USUAL MAXIMUM REPLACEMENT
A4619	One/month
A4621	One/month
A7003	Two/month
A7004	Two/month (in addition to A7003)
A7005	One/6 months
A7006	One/month
A7010	One unit (100 ft.)/2 months

ACCESSORY	USUAL MAXIMUM REPLACEMENT
A7011	One/year
A7012	Two/month
A7013	Two/month
A7014	One/3 months
A7015	One/month
A7016	Two/year
A7017	One/3 years
E1372	One/3 years

Inhalation Drugs and Solutions:

For all inhalation drugs and solutions, claims for dispensed quantities greater than would be reasonable based on usual suggested dosing guidelines will be denied as not medically necessary unless accompanied by medical necessity documentation justifying these unexpected quantities. The pharmacist is responsible for assessing how much inhalation solution a patient is actually using. Considering this information, the pharmacist is responsible for assuring that the patient usually has no more than one month's supply on hand at any time.

The following table represents the maximum milligrams/month of inhalation drugs that would be reasonably billed for each nebulized drug. Claims for more than these amounts of drugs will be denied as not medically necessary unless accompanied by documentation which justifies a larger amount in the individual case.

INHALATION DRUG	MAXIMUM MILLIGRAMS/MONTH
Acetylcysteine	up to 74 grams/month
Albuterol	up to 465 mg./month
Atropine	up to 186 mg./month
Bitolterol	up to 434 mg./month
Cromolyn sodium	up to 2480 mg./month (248 units/month)
Dornase alpha	up to 78 mg./month
Glycopyrrolate	up to 75 mg./month
Ipratropium bromide	up to 93 mg./month
Isoetharine	up to 930 mg./month
Isoproterenol	up to 450 mg./month
Levalbuterol	up to 232.5 mg./month (465 units/month)
Metaproterenol	up to 2800 mg./month (280 units/month)
Pentamidine	up to 300 mg./month
Terbutaline	up to 186 mg./month
Sterile saline or water, up to 5cc/unit (J7051)	up to 186 units/month
Saline solution, metered dose, 10 ml/unit (A7019)	up to 60 units/month
Distilled water, sterile water, or sterile saline in large volume nebulizer	up to 18 liters/month

When a "concentrated form" of an inhalation drug is dispensed, separate saline solution (J7051 or A7019) used to dilute it will be separately reimbursed. Saline dispensed for the dilution of concentrated nebulizer drugs must be billed on the same claim as the drug(s) being diluted. If the unit dose form of the drug is dispensed, separate saline solution (J7051 or A7019) will be denied as not medically necessary. Water or saline in 1000 ml quantities (A7018 or A7020) are not appropriate for use by patients to dilute inhalation

Manuals

<<<BACK

Chapter 20 - Intrapulmonary Percussive Ventilation System

View Attachments

Contractor Policy Number IPV
Contractor Name Palmetto GBA
Contractor Number 00885
Contractor Type DMERC

RMRP Title

Intrapulmonary Percussive Ventilation System

CMS National Coverage Policy

CIM 60-21

Primary Geographic Jurisdiction

DMERC Region C (Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands)

CMS Region

VI (Dallas), IV (Atlanta), II (New York), VIII (Denver)

CMS Consortia

Southern, Northeast, Western

Original Policy Effective Date

Claims with dates of service on or after July 1, 2002.

Original Policy Ending Date

NA

Revision Effective Date

NA

Revision Ending Date

NA

LMRP Description

An intrapulmonary percussive ventilation system (IPV) delivers a series of pressurized gas minibursts at rates greater than 100 cycles per minute to the respiratory tract.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

An intrapulmonary percussive ventilator (IPV) (E0481) is not covered. These devices have not been demonstrated to be reasonable and necessary in the home setting.

HCPCS Section and Benefit Category

Durable Medical Equipment

HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

E0481 Intrapulmonary pulmonary percussive ventilation system and related accessories.

Original Policy Ending Date

NA

Revision Effective Date

NA

Revision Ending Date

NA

LMRP Description

An intrapulmonary percussive ventilation system (IPV) delivers a series of pressurized gas minibursts at rates greater than 100 cycles per minute to the respiratory tract.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

An intrapulmonary percussive ventilator (IPV) (E0481) is not covered. These devices have not been demonstrated to be reasonable and necessary in the home setting.

HCPCS Section and Benefit Category

Durable Medical Equipment

HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

E0481 Intrapulmonary pulmonary percussive ventilation system and related accessories.

ICD-9 Codes and Diagnoses that Support Medical Necessity

None

Reasons for Denial

Intrapulmonary percussive ventilation systems will be denied as not medically necessary.

Coding Guidelines

E0481 includes the compressor, hand held units, tubing and all related accessories. This includes both systems in which the minibursts of air are generated by the compressor and systems in which the minibursts of air are generated by a hand held percussive nebulizer used with a standard high-pressure compressor.

Supplier should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §1395l (e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

The supplier must have a signed physician order to submit a claim to Medicare.

Utilization Guidelines

NA

Sources of Information and Basis for Decision

CMS National Coverage Determination (CIM 60-21) Intrapulmonary Percussive Ventilation (IPV) not covered

Advisory Committee Notes

NA

Start Date of Comment Period

NA

End Date of Comment Period

NA

Start Date of Notice Period

Revision History

NA

<<<BACK

Region C DMEPOS Supplier Manual (updated through Winter 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19 - Oxygen
.....Chapter 20 - Intrapulmonary Percussive Ventilation System

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<<BACK

Chapter 21 - Nebulizer

View Attachments

Chapter 21 contains the nebulizer medical policy. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Nebulizers

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

Equipment

E0565	Compressor, air power source, for equipment which is not self-contained or cylinder driven
E0570	Nebulizer with compressor
E0571	Aerosol compressor, battery powered, for use with small volume nebulizer
E0572	Aerosol compressor, adjustable pressure, light duty for intermittent use
E0574	Ultrasonic generator with small volume ultrasonic nebulizer
E0575	Nebulizer, ultrasonic, large volume
E0585	Nebulizer, with compressor and heater

Accessories

A4619	Face tent

A4621	Tracheostomy mask or collar
A7003	Administration set, small volume nonfiltered pneumatic nebulizer, disposable
A7004	Small volume nonfiltered pneumatic nebulizer, disposable
A7005	Administration set, small volume nonfiltered pneumatic nebulizer, non-disposable
A7006	Administration set, small volume filtered pneumatic nebulizer
A7007	Large volume nebulizer, disposable, unfilled, used with aerosol compressor
A7008	Large volume nebulizer, disposable, prefilled, used with aerosol compressor
A7009	Reservoir bottle, non-disposable, used with large volume ultrasonic nebulizer
A7010	Corrugated tubing, disposable, used with large volume nebulizer, 100 feet
A7011	Corrugated tubing, non-disposable, used with large volume nebulizer, 10 feet
A7012	Water collection device, used with large volume nebulizer
A7013	Filter, disposable, used with aerosol compressor
A7014	Filter, non-disposable, used with aerosol compressor or ultrasonic generator
A7015	Aerosol mask, used with DME nebulizer
A7016	Dome and mouthpiece, used with small volume ultrasonic nebulizer
A7017	Nebulizer, durable, glass or autoclavable plastic, bottle type, not used with oxygen
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1372	Immersion external heater for nebulizer

Inhalation Drugs:

A7018	Water, distilled, used with large volume nebulizer, 1000 ml
A7019	Saline solution, per 10 ml, metered dose dispenser, for use with inhalation drugs
A7020	Sterile water or sterile saline, 1000 ml, used with large volume nubulizer
E0590	Dispensing fee for covered drug administered through DME nebulizer
J2545	Pentamidine isethionate, inhalation solution, per 300 mg, administered through DME
J7051	Sterile saline or water, up to 5 cc

J7608	Acetylcysteine, inhalation solution administered through DME, unit dose form, per gram
J7618	Albuterol, all formulations including separated isomers, inhalation solution administered through DME, concentrated form, per 1 mg. (albuterol) or per 0.5 mg. (levalbuterol)
J7619	Albuterol, all formulations including separated isomers, inhalation solution administered through DME, unit dose form, per 1 mg. (albuterol) or per 0.5mg. (levalbuterol)
J7622	Beclomethasone, inhalation solution administered through DME, unit dose form, per milligram
J7624	Betamethasone, inhalation solution administered through DME, unit dose form, per milligram
J7626	Budesonide inhalation solution, administered through DME, unit dose form, 0.25 mg.
J7628	Bitolterol mesylate, inhalation solution administered through DME, concentrated form, per milligram
J7629	Bitolterol mesylate, inhalation solution administered through DME, unit dose form, per milligram
J7631	Cromolyn sodium, inhalation solution administered through DME, unit dose form, per 10 milligrams
J7635	Atropine, inhalation solution administered through DME, concentrated form, per milligram
J7636	Atropine, inhalation solution administered through DME, unit dose form, per milligram
J7637	Dexamethasone, inhalation solution administered through DME, concentrated form, per milligram
J7638	Dexamethasone, inhalation solution administered through DME, unit dose form, per milligram
J7639	Dornase alpha, inhalation solution administered through DME, unit dose form, per milligram
J7641	Flunisolide, inhalation solution administered through DME, unit dose, per milligram
J7642	Glycopyrrolate, inhalation solution administered through DME, concentrated form, per milligram
J7643	Glycopyrrolate, inhalation solution administered through DME, unit dose form, per milligram
J7644	Ipratropium bromide, inhalation solution administered through DME, unit dose form, per milligram
J7648	Isoetharine HCL, inhalation solution administered through DME, concentrated form, per milligram
J7649	Isoetharine HCL, inhalation solution administered through DME, unit dose form, per milligram
J7658	Isoproterenol HCL, inhalation solution administered through

	DME, concentrated form, per milligram
J7659	Isoproterenol HCL, inhalation solution administered through DME, unit dose form, per milligram
J7668	Metaproterenol sulfate, inhalation solution administered through DME, concentrated form, per 10 milligrams
J7669	Metaproterenol sulfate, inhalation solution administered through DME, unit dose form, per
	10 milligrams
J7680	Terbutaline sulfate, inhalation solution administered through DME, concentrated form, per milligram
J7681	Terbutaline sulfate, inhalation solution administered through DME, unit dose form, per milligram
J7682	Tobramycin, unit dose form, 300 mg, inhalation solution (administered through DME)
J7683	Triamcinolone, inhalation solution administered through DME, concentrated form, per milligram
J7684	Triamcinolone, inhalation solution administered through DME, unit dose form, per milligram
J7699	NOC drugs, inhalation solution administered through DME

HCPCS MODIFIERS

KO	Single drug unit dose formulation
KP	First drug of a multiple drug unit dose formulation
KQ	Second or subsequent drug of a multiple drug unit dose formulation

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issue Manual 60-9

DEFINITIONS

Equipment

In this policy, the actual equipment (i.e., electrical device) will generally be referred to as either a compressor (when nebulization of liquid is achieved by means of air flow) or as a generator (when nebulization of liquid is achieved by means of ultrasonic vibrations). The term nebulizer is generally used for the actual chamber in which the nebulization of liquid occurs and is an accessory to the equipment. The nebulizer is attached to an aerosol compressor or an ultrasonic generator in order to achieve a functioning delivery system for aerosol therapy.

Code E0565 describes an aerosol compressor which can be set for pressures

above 30 psi at a flow of 6-8 L/m and is capable of continuous operation.

A nebulizer with compressor (E0570) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It is only AC powered.

A portable compressor (E0571) is an aerosol compressor which delivers a fixed, low pressure and is used with a small volume nebulizer. It must have battery or DC power capability and may have an AC power option.

A light duty adjustable pressure compressor (E0572) is a pneumatic aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m, but is capable only of intermittent operation.

Code E0574 describes an ultrasonic generator used with a small volume chamber for medication delivery which is capable only of intermittent operation.

Code E0575 describes a large volume ultrasonic nebulizer system which is used for medication and humidification delivery, and which is capable of continuous operation.

Accessories

Code A7003, A7005, and A7006 include the lid, jar, baffles, tubing, T-piece and mouthpiece. In addition, code A7006 includes a filter.

Code A7004 includes only the lid, jar and baffles.

Code A7012 describes a device to collect water condensation which is placed in line with the corrugated tubing used with a large volume nebulizer.

Inhalation Drugs

Unit dose form of an inhalation drug or a combination of drugs is one in which the medication is dispensed to a patient (1) in a bottle/vial/ampule which contains the dose usually used for a single inhalation treatment, and (2) in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent.

Concentrated form of a drug used for inhalation is one in which the drug is dispensed to a patient in a concentration which requires that a separate diluent (usually saline) be added to the nebulizer when the drug is administered to a patient.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) fit into a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis

or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

A small volume nebulizer (A7003, A7004, A7005) and related compressor (E0570, E0575) are covered when:

a) It is medically necessary to administer beta-adrenergics, anticholinergics, corticosteroids, and cromolyn for the management of obstructive pulmonary disease (ICD-9 diagnosis codes 491.0 - 505), or
b) It is medically necessary to administer gentamicin, tobramycin, amikacin, or dornase alfa to a patient with cystic fibrosis (ICD-9 diagnosis code 277.00) or
c) It is medically necessary to administer pentamidine to patients with HIV (ICD-9 code 042), pneumocystosis (ICD-9 diagnosis code 136.3), and complications of organ transplants (ICD-9 diagnosis codes 996.8-996.89), or
d) It is medically necessary to administer mucolytics (other than dornase alpha) for persistent thick or tenacious pulmonary secretions (ICD-9 diagnosis code 786.4).

Use of inhalation drugs, other than those listed above, will be denied as not medically necessary.

For criterion (a) to be met, the physician must have considered use of a metered dose inhaler (MDI) with and without a reservoir or spacer device and decided that, for medical reasons, it was not sufficient for the administration of needed inhalation drugs. The reason for requiring a small volume nebulizer and related compressor/generator instead of or in addition to an MDI must be documented in the patient's medical record and be available to the DMERC on request.

If none of the drugs used with a nebulizer are covered, the nebulizer and its accessories/supplies will be denied as not medically necessary.

A large volume nebulizer (A7017), related compressor (E0565 or E0572), and water or saline (K0182 or K0529) are covered when it is medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis (ICD-9 diagnosis code 277.00), bronchiectasis (ICD-9 diagnosis code 494 or 748.61), or a tracheostomy (ICD-9 diagnosis code V44.0 or V55.0), or a tracheobronchial stent (ICD-9 diagnosis code 519.1). Combination code E0585 will be covered for the same indications. An E0565 or E0572 compressor and filtered nebulizer (A7006) are also covered when it is medically necessary to administer pentamidine to patients with HIV (ICD-9 diagnosis code 042). If a large volume nebulizer, related compressor/generator, and water or saline are used predominantly to

provide room humidification it will be denied as noncovered.

Because there is no proven medical benefit to nebulizing particles to diameters smaller than achievable with a pneumatic model, when a small volume ultrasonic nebulizer (E0574) is ordered, it will be reimbursed at the least costly alternative of a pneumatic compressor (E0570).

Similarly, a large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor. However, since code E0575 is in a different payment category than pneumatic compressors, payment for a least costly alternate cannot be made. Therefore, when an E0575 nebulizer is provided, it will be denied as not medically necessary as will any related accessories and supplies.

A battery powered compressor (E0575) is rarely medically necessary. If this compressor is provided without accompanying documentation which justifies its medical necessity, and the coverage criteria for code E0570 are met, payment will be based on the allowance for the least costly medically acceptable alternative, E0570.

Other uses of compressors/generators will be considered individually on a case by case basis, to determine their medical necessity.

Accessories:

A large volume pneumatic nebulizer (E0580) and water or saline (A7018 or A7020) are not separately payable and should not be separately billed when used for patients with rented home oxygen equipment.

Disposable large volume nebulizers (A7007 and A7008) are noncovered under the DME benefit because they are convenience items. A non-disposable unfilled nebulizer (A7017 or E0585) filled with water or saline (A7018, A7020) by the patient/caregiver is an acceptable alternative.

Kits and concentrates for use in cleaning respiratory equipment will be denied as noncovered.

Accessories are separately payable if the related aerosol compressor and the individual accessories are medically necessary. The following table lists the compressor/generator which is related to the accessories described. Other compressor/generator/accessory combinations are considered medically unnecessary.

Compressor/Generator	Related Accessories
E0565	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015, A7017, E1372
E0570	A4621, A7003, A7004, A7005, A7006, A7013, A7015

E0585	A4619, A4621, A7006, A7010, A7011, A7012, A7014, A7015
E0572	A7006, A7014
E0574	A7014, A7016
E0575	A4621, A7003, A7004, A7005, A7006, A7013, A7015

This array of accessories represents all possible combinations but it may not be appropriate to bill any or all of them for one device.

The following table lists the usual maximum frequency of replacement for accessories. Claims for more than the usual maximum replacement amount will be denied as not medically necessary unless the claim is accompanied by documentation which justifies a larger quantity in the individual case.

Accessory	Usual Maximum Replacement
A4619	One/month
A4621	One/month
A7003	Two/month
A7004	Two/month (in addition to A7003)
A7005	One/6 months
A7006	One/month
A7010	One unit (100 ft.)/2 months
A7011	One/year
A7012	Two/month
A7013	Two/month
A7014	One/3 months
A7015	One/month
A7016	Two/year
A7017	One/3 years
E1372	One/3 years

Inhalation Drugs and Solutions:

For all inhalation drugs and solutions, claims for dispensed quantities greater than would be reasonable based on usual suggested dosing guidelines will be denied as not medically necessary unless accompanied by medical necessity documentation justifying these unexpected quantities. The pharmacist is responsible for assessing how much inhalation solution a patient is actually using. Considering this information, the pharmacist is responsible for assuring that the patient usually has no more than one month's supply on hand at any time.

The following table represents the maximum milligrams/month of inhalation drugs that would be reasonably billed for each nebulized drug. Claims for more than these amounts of drugs will be denied as not medically necessary unless accompanied by documentation which justifies a larger amount in the individual case.

Inhalation Drug	**Maximum Milligrams/month**
Acetylcysteine	up to 74 grams/month
Albuterol	up to 465 mg./month
Atropine	up to 186 mg./month
Bitolterol	up to 434 mg./month
Cromolyn sodium	up to 2480 mg./month (248 units/month)
Dornase alpha	up to 78 mg./month
Glycopyrrolate	up to 75 mg./month
Ipratropium bromide	up to 93 mg./month
Isoetharine	up to 930 mg./month
Isoproterenol	up to 450 mg./month
Levalbuterol	up to 232.5 mg./month (465 units/month)
Metaproterenol	up to 2800 mg./month (280 units/month)
Pentamidine	up to 300 mg./month
Terbutaline	up to 186 mg./month
Sterile saline or water, up to 5cc/unit (J7051)	up to 186 units/month
Saline solution, metered dose, 10 ml/unit (A7019)	up to 60 units/month
Distilled water, sterile water, or sterile saline in large volume nebulizer	up to 18 liters/month

When a "concentrated form" of an inhalation drug is dispensed, separate saline solution (J7051 or A7019) used to dilute it will be separately reimbursed. Saline dispensed for the dilution of concentrated nebulizer

drugs must be billed on the same claim as the drug(s) being diluted. If the unit dose form of the drug is dispensed, separate saline solution (J7051 or A7019) will be denied as not medically necessary. Water or saline in 1000 ml quantities (A7018 or A7020) are not appropriate for use by patients to dilute inhalation drugs and will therefore be denied as not medically necessary if used for this purpose. These codes are only medically necessary when used in a large volume nebulizer (A7017 or E0585).

Albuterol, bitolterol, epinephrine, isoetharine, isoproterenol, metaproterenol, and terbutaline are all bronchodilators with beta-adrenergic stimulatory effect. It would rarely be medically necessary for a patient to be using more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Ipratropium bromide, atropine, and glycopyrrolate are all anticholinergics. It would rarely be medically necessary for a patient to be using any more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary without documentation of medical necessity.

Dornase alpha is covered for patients with cystic fibrosis (ICD-9-CM diagnosis code 277.00) who have a history of 2 respiratory infections requiring parenteral antibiotics during the year prior to initiation of dornase alpha and have a forced vital capacity equal to or greater than 40% of predicted value.

Because of the difference in preparation costs, the allowance per mg. for a single drug dispensed as a unit dose formulation (e.g. J7619KO) will be higher than the allowance per mg. for the same drug dispensed in a concentrated form (e.g. J7618). However, if multiple inhalation drugs are dispensed in a single container, only one of the drugs (i.e., that drug billed with the KP modifier) will be reimbursed at the higher allowance, whereas the other drug(s) (i.e., those billed with the KQ modifier) will be reimbursed at the same allowance as the concentrate. (See Coding Guidelines section for explanation of the KO, KP, and KQ modifiers.)

A monthly dispensing fee (E0590) for each covered drug or combination of drugs used in a nebulizer will be paid in addition to payment for the drug or drugs. This dispensing fee will be based on the drug dispensed, and not on the number of unit dose vials dispensed. Also, if two or more drugs are combined in single unit dose vials, only one dispensing fee will be paid per drug combination per month. The dispensing fee(s) must be billed on the same claim as the dispensed inhalation drug(s). A dispensing fee is not separately billable or payable for saline, whether used as a diluent or for humidification therapy.

Charges for the drugs, diluent, and dispensing fees may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local

laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DMERC for nebulizer drugs.

Aerosol compressors and small volume ultrasonic generators will be grandfathered according to the provisions of the general DMERC Grandfathering policy, Sections A and B, if the approval did not conflict with national Medicare policy. In addition, if equipment with dates of service before the effective date of this policy was approved by the DMERC, it will also continue to be reimbursed. Appropriate accessories, supplies, and drugs will be covered if the equipment had been approved by the local carrier or the DMERC and the approval did not conflict with national policy. However, large volume ultrasonic generators (E0575) are not covered unless payment for the equipment was made by a local carrier prior to transition to the DMERC. For all items, even when coverage is grandfathered or continued, the frequency parameters listed in the policy will be applied. Also, coding for inhalation drugs and resulting reimbursement will be according to the DMERC policy.

CODING GUIDELINES

The billing unit for most inhalation drugs is per milligram (mg.) of the drug dispensed. The billing unit of J7631, J7668, and J7669 is per 10 milligrams (10 mg.) of the drug dispensed. The billing unit of J7608 is per gram (gm.) of the drug dispensed. The billing unit of J2545 and J7682 is per 300 milligrams (300 mg.) of the drug dispensed.

The billing units of J7618, J7619 for the standard formulation of albuterol is 1 mg. = 1 unit. The billing unit of J7618, J7619 for levalbuterol is 1 mg. = 2 units.

When inhalation drugs are dispensed as a single drug formulation, the coding of a unit dose form or a concentrated form (see Definitions section) is determined by the formulation of the drug as it is dispensed to the patient. If a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol) which is then dispensed to the patient in single-dose bottles/vials/ampules, the inhalation solution is billed as the unit dose form, not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. When two or more drugs are combined by a pharmacist and dispensed to the patient in the same unit dose container, all of the drugs are billed using the unit dose form code. However, the KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s). When two or more drugs are combined, the use of the KP and KQ modifiers should result in a combination that yields the lower cost to the beneficiary.

Whenever a unit dose form code is billed, it must have either a KO, KP, or KQ modifier. If a unit dose code does not have one of these modifiers, it

will be denied as an invalid code. The KO, KP, and KQ modifiers are not used with the concentrated form codes.

The concentration of the drug in the dispensed solution can be converted to mg. or gm. as follows: A solution with a labeled concentration of 1% has ten (10) mg. of drug in each milliliter (ml.) of solution. Therefore, a 0.083% standard formulation albuterol solution has 0.83 mg. of standard formulation albuterol in each ml. of solution. Since albuterol 0.083% solution typically comes in a 3 ml. vial/ampule, each vial/ampule contains 2.5 mg. of albuterol (3 x .83 = 2.5). If a pharmacist provides 120 ampules of 0.083% albuterol solution each containing 3 ml., the billed units of service would be 300 (2.5 x 120) units (1 unit = 1 mg.) of code J7619KO. One unit of E0590 would be billed, which would represent the dispensing fee for the albuterol for the entire month.

When billing unit dose solutions which combine two or more drugs in a single container, each drug must be listed on a separate claim line. For example, if a pharmacist provides 120 ampules of a solution containing a combination of 2.5 mg. of albuterol and 20 mg. of cromolyn in each 3 ml. ampule, the pharmacist would bill J7619KQ 300 units for the albuterol (2.5 mg. x 120 doses = 300) (1 unit = 1 mg.) and J7631KP (unit dose cromolyn) 240 units (20 mg/amp) 10 mg./unit x 120 = 240)(1 unit = 10 mg.) for the cromolyn. One unit of E0590 would be billed which represents the dispensing fee for the combined solution for the entire month. There should be no separate billing for saline diluent.

Pharmacists should note that the correct concentration figure must be used to determine the number of mg. of drug dispensed. For example, if a pharmacist takes 0.5 ml. of a concentrated 0.5% albuterol solution and dilutes it with 2.5 ml. of saline to give a 3 ml. unit dose solution which is dispensed to the patient, each vial contains 2.5 mg. of albuterol (0.5 ml. x 5.0 mg/ml = 2.5 mg.), not 15 mg. (3 x 5.0).

When a drug is provided in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent in a multidose container, use code J7699.

Code J7699 is also used for an inhalation drug administered by a nebulizer which does not have a valid specific J or K code. If two or more drugs are combined in the same unit dose container, bill specific J or K codes when possible and J7699 only for individual drugs which do not have a specific J or K code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate specific J or K codes will be denied for invalid coding.

Code E0585 is used when a heavy duty aerosol compressor (E0565), durable bottle type large volume nebulizer (A7017), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code A7017 is billed for a durable, bottle type nebulizer when it is used with a E0572 compressor or a separately billed E0565 compressor. Code

A7017 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as A7017, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Code A4323 (Sterile saline irrigation solution, 1000 ml) is not valid for saline solutions used with nebulizers.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for all equipment, accessories, drugs, and other supplies related to nebulizer therapy must be signed and dated by the ordering physician and kept on file by the supplier. The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container, or (b) the name of the drug and the number of milligrams/grams of drug in the dispensed solution and the volume of solution in that container. Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. Examples of (b) would be: albuterol 1.25 mg. in 3 ml. saline; or albuterol 2.5 mg. and cromolyn 20 mg. in 3 ml. saline. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml. qid and prn - max 6 doses/24 hr.; or one ampule q 4 hr prn; or 0.5 ml. diluted with saline to 3.0 ml. tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

A narrative diagnosis and/or an ICD-9 diagnosis code describing the condition must be present on each order. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

The patient's medical record must contain information which supports the

medical necessity for all equipment, accessories, drugs, and other supplies that are ordered. Except for the situations described below, this information does not have to be submitted with the claim but should be available to the DMERC on request.

Claims for E0571 must be accompanied by documentation of the need for the battery feature.

Claims to the DMERC for E0575 which were approved by a local carrier prior to transition to the DMERC must be submitted hardcopy, with a copy of the documentation demonstrating previous payment for the equipment by the local carrier.

When billing for quantities of nebulized inhalation drugs or nebulizer accessories and supplies greater than those described in the policy as the usual maximum amounts, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity for the higher utilization.

If more than one beta-adrenergic or more than one anticholinergic inhalation drug is billed during the same month, each claim must be accompanied by a copy of the prescription(s) and physician narrative documentation supporting the medical necessity of concurrent use.

When code E1399 is billed for miscellaneous equipment or accessories, the claim must be accompanied by a clear description of the item including the manufacturer, the model name/number if applicable, and the medical necessity of the item for that patient. When Not Otherwise Classified (NOC) drug code J7699 is billed for miscellaneous inhalation drugs, the claim must be accompanied by the detailed order information described above, a clear statement of the number of ampules/bottles of solution dispensed, and documentation of the medical necessity of the drug for that patient.

In all of the situations listed above, the documentation should be attached to each hard copy claim (as when physician narrative documentation is required) or entered in the HA0 record of each electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after April 1, 2002.

This is a revision of a previously published policy.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Winter 2002)
....Change of Address Notification Form